

AD _____

Award Number: DAMD17-98-1-8100

TITLE: Development and Evaluation of Computer-Based Versions of
the Decision Board for Early Breast Cancer

PRINCIPAL INVESTIGATOR: Timothy J. Whelan, M.D.

CONTRACTING ORGANIZATION: McMaster University
Hamilton, Ontario L8N3Z5 Canada

REPORT DATE: October 1999

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

DTIC QUALITY INSPECTED 4

20010108 124

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE October 1999	3. REPORT TYPE AND DATES COVERED Annual (1-Oct-98 - 30-Sep-99)	
4. TITLE AND SUBTITLE Development and Evaluation of Computer-Based Versions of the Decision Board for Early Breast Cancer			5. FUNDING NUMBERS DAMD17-98-1-8100	
6. AUTHOR(S) Timothy J. Whelan, M.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) McMaster University Hamilton, Ontario L8N3Z5 Canada E-MAIL:			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES This report contains colored photos				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited				12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words) The objectives of this study are to develop i) computer-based versions of the Decision Boards for (a) surgical treatment of breast cancer; (b) chemotherapy for node-negative breast cancer, and (c) chemotherapy for premenopausal node-positive breast cancer; and ii) to compare the relative effectiveness of the computer-based versions with standard Decision Boards for women with early breast cancer. In our first year, all three standard Decision Boards were updated based on a review of the literature. Focus groups were held with physicians and women with breast cancer to identify key characteristics of computer-based versions. A computer-based version of the surgery Decision Board was produced and is entering feasibility testing. Computer-based versions of the two chemotherapy Boards are currently being developed. Following feasibility testing, the instruments will be formally evaluated in a randomized trial.				
14. SUBJECT TERMS Breast Cancer			15. NUMBER OF PAGES 81	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

U Where copyrighted material is quoted, permission has been obtained to use such material.

U Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

U Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

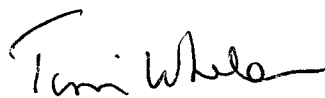
N/A In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

X For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.



PI - Signature

11/05/99

Date

Table of Contents

FRONT COVER	1
REPORT DOCUMENTATION PAGE	2
FOREWORD	3
TABLE OF CONTENTS	4
INTRODUCTION.....	5
BODY.....	6
KEY RESEARCH ACCOMPLISHMENTS.....	13
REPORTABLE OUTCOMES	14
CONCLUSIONS	16
REFERENCES.....	17
APPENDICES	19

Introduction

Women with breast cancer have increasingly indicated a desire for more information about their disease and need to be involved in decisions about their care. The main objective of the study is to further enhance information transfer between the doctor and patient giving women with early stage breast cancer an opportunity to more fully participate in treatment decision making. In this study, computer-based versions of decision aids (called Decision Boards) are being developed for three decision-making scenarios: 1) mastectomy versus lumpectomy plus radiation, 2) chemotherapy for node-negative breast cancer (chemotherapy versus no chemotherapy), and 3) chemotherapy for premenopausal node-positive breast cancer (CEF versus CMF versus AC versus no treatment). The computer versions will be based on previous Decision Boards and will be developed through an iterative process with focus groups of patients and clinicians. Following development, feasibility testing will be performed to assess overall patient comprehension and acceptability. The computer versions will then be compared with standard versions in a randomized trial. These computer-based versions will not merely adapt or replicate standard versions of the Decision Boards, but rather will, in fact, be new instruments with their own unique potential and thus require evaluation. We hypothesize that the many advantages of computer-based versions will result in improved patient understanding as well as patient and physician satisfaction. We predict that any initial reluctance that may be felt by some towards computer-based applications of these Decision Boards will be offset or overcome by improvements in understanding and satisfaction.

Body

Progress made towards accomplishing the first year's objectives is outlined below. Considerable progress has been made in updating current instruments, and computerization of the surgery Decision Board and the chemotherapy Board for node-positive breast cancer.

Task 1: Development of Computer-Based Version of Decision Boards and Updating the Standard versions of the Decision Board Currently Used at the HRCC and Outlying Communities (Months 1 – 12)

- **Perform a systematic review of the three treatment options (months 1)**

Surgery Decision Board for the Choice of Mastectomy versus Lumpectomy Plus Radiation - An extensive evaluation of the surgery Decision Board in the community was published in the Journal of Clinical Oncology¹ (see Appendix 1). The instrument was used by seven surgeons in different communities in Ontario over an 18-month period. Patients and surgeons were interviewed regarding acceptability of the instrument, and the rates of breast conserving surgery performed by surgeons before and after the introduction of the instrument were compared. The Decision Board was administered to 175 patients; 98% reported that the instrument was easy to understand and 81% indicated that it helped them make a decision. Surgeons found the Board helpful in presenting information to patients in 91% of consultations. Surprisingly, the rate of breast conserving surgery decreased when the Decision Board was introduced into the community (88% vs 73%, $p = 0.001$). (This was attributed, in part, to the very high rate of breast conserving surgery performed prior to the introduction of the Decision Board as described in the publication.) The instrument was well accepted by patients and surgeons, and easily applied in the community. It appeared to improve communication and facilitate shared decision making (see Appendix 2). Since publication of the

original article, there has been extensive interest in the surgery Decision Board from community surgeons (see letters attached – Appendix 3). A description of the study and the instrument was highlighted in an article in the Bulletin from the American College of Surgeons.²

A review of the literature revealed no additional newly published studies comparing mastectomy to lumpectomy plus radiation. Feedback about the content of the instrument with respect to the description of treatments and scheduling in current practice was obtained from community surgeons. Minor changes in wording were made to reflect this. The Decision Board is currently undergoing a rigorous evaluation in a randomized trial in Ontario comparing the instrument to the traditional consultation without the instrument.³

Chemotherapy for Node-negative Breast Cancer Decision Board (Chemotherapy versus No Treatment) - The original instrument focused primarily on high risk (ER negative) node-negative patients.⁴ A systematic review revealed a new randomized trial NSABP B-20 evaluating the role of chemotherapy in addition to Tamoxifen in ER positive node-negative patients.⁵ The original instrument has now undergone extensive changes to include ER positive patients reflecting the choice of the addition of chemotherapy to Tamoxifen. From the review of our database, three different risk categories have been identified (see Appendix 4). A randomized trial comparing this instrument to current practice is approaching completion.⁶

Chemotherapy for Premenopausal Node-positive Breast Cancer Decision Board - Development and preliminary evaluation of this instrument was recently published⁷ (see Appendix 5). The review of the literature has identified the National Cancer Institute of Canada (NCIC) MA-5 study indicating improved survival with cyclophosphamide, epirubicin, and fluorouracil (CEF) chemotherapy over cyclophosphamide, methotrexate and fluorouracil (CMF), the latter of which is commonly used in Canada.⁸ This instrument is currently being revised to reflect this option. Results of the Intergroup study comparing adriamycin and cyclophosphamide (AC) plus paclitaxel to AC alone has been

published in abstract form.⁹ AC plus Taxol is not currently approved for use in Canada, and so has not yet been included in the instrument. The instrument was updated to include latest data on recurrence and incidence of side effects, such as leukemia, cardiomyopathy, and febrile neutropenia.^{8,10-12} Additional panels to the new instrument are included in Appendix 6.

- **Conduct focus groups (months 1-3)**

Surgery Decision Board Focus Groups with Surgeons – Two focus groups have been held with surgeons regarding the computerized Decision Board. At the first focus group, surgeons discussed the advantages and disadvantages of the standard surgery Decision Board and suggested changes to improve its functionality. For example, suggestions included less detail on surgical drains and scheduling of radiation due to changes in practice. Computerization of the instrument was introduced and surgeons were asked to make recommendations about further modifications that this technology could incorporate. Suggestions included i) maintain an overview panel; ii) permit different ways to access the information; and iii) use key words to provide more detailed information, e.g., breast reconstruction. Based on this feedback, the computerized version was developed (see below). The instrument was presented to surgeons at the second focus group. Further suggestions were made for modification including i) ability to have a comparison panel screen and allow synopsis panels to appear on the overview once each panel was entered. These changes have been incorporated (see below). A focus group with patients has been organized to provide additional feedback.

Chemotherapy Node-negative Decision Board – Two focus groups were held with physicians and patients regarding modifications to the instrument based on the literature review. The NSABP B-20 results were discussed in detail. It was suggested that a description of Tamoxifen on the introductory card prior to describing chemotherapy be included (see Appendix 4).

Chemotherapy Node-positive Decision Board – Two focus groups were held with medical oncologists who treat breast cancer. Suggestions were to i) decrease written language and increase the use of figures to make the display more visual; ii) present probability of side effects and recurrence in graphical format using bar graphs and/or pie charts; and iii) present more common (and less serious) side effects separately from less common (more serious) side effects.

Two focus groups have also been held with patients. The purpose of the first focus group was to determine from the patient's perspective relevant information that should be included in the computerized version. Patients' recommendations were i) to provide a description of outcomes with no chemotherapy; ii) to include all different options, i.e., CMF, AC, CEF; iii) to provide data on each side effect and not overall quality of life (as patients found this difficult to interpret); and iv) to provide information on treatments available for side effects.

At the second focus group, a prototype of the standard instrument was developed for patients. A further recommendation was made to describe recurrence data separately as pie charts rather than bar graphs. Based on this feedback, a computerized version is currently being developed (see below).

- **Development of computerized versions of Decision Boards**

The intention here was first to develop a prototype with the surgery Decision Board and then to develop the additional instruments. Dr. Sebaldt has taken the lead in programming the instrument. Under his direction, a senior computer programmer was consulted and a prototype developed. Principles for the development of the instrument included maximum legibility of text and numbers, minimization of screen clutter; complete user orientation at all times within the system; and obvious user navigation from all locations within the system.

Programs for the computerized decision boards are being written using the Pascal-based Borland

Delphi Version 3. This object-oriented programming environment has permitted us to retain the positive attributes of the standard versions while allowing us to add features unique to the computer interface. Through the use of active components in the visual display (i.e., buttons, tabs and hypertext links), the user is given access to progressive depths of information on selected topics. Microsoft "Wizard"-like sequences grant the user full navigational control. For chemotherapy interfaces, patients are given information specific to their risk category after entering individual tumor characteristics. These programs are being designed for a Windows-based platform and are easily accessed through a native standalone executable program file.

Surgery Decision Board – As in the standard version, the computerized version consists of panels of information describing the patient's two treatment options, mastectomy or lumpectomy plus radiation; the associated side effects; and results of treatment choice for the breast and for survival. Sample panels are provided in Appendix 7. Based on suggestions from the focus groups, an overview screen was provided allowing access to all panels of information. For each panel accessed, a summary panel replaces it providing the user with information about panels they have already accessed. Notebook tabs are used to afford full orientation and obvious one click access to all programs. More detailed second level information is provided on appropriate key words using pop up windows. The surgery prototype is now developed. The plan will be to undergo minor modifications based on further testing in the field.

Chemotherapy Decision Boards – In view of the more detailed information required for the node-positive instrument, it was felt that this should be developed first. A prototype is currently being programmed. As this instrument will provide detailed information about probabilities of outcomes for patients based on individual characteristics, it requires a further level of programming. In addition, more detailed information will be provided on probabilities of different side effects

The node-negative instrument will largely be based on the program being developed for the node-

positive instrument and, to a large extent, will provide similar information.

- **Field testing of instruments on 9-15 clinicians and 48 patients not previously involved in the developmental state to determine if the instruments are acceptable and non-threatening to patients and physicians at the decision point (months 6 – 12)**

Based on recommendations from the focus groups, requirements for each computer were large high resolution screen, quick access, durability. Four “Dell” Inspiron 7500 laptop computers with Celeron processors have been purchased for field testing. The model is a 433 Mhz processor with 128mb of memory, a 6.5 Gig hard drive, CD-ROM/Floppy combo, network/modem, and 17” screen.

Surgery Decision Board – The surgery instrument is currently being pilot tested in three surgical outpatient clinics in the community. The plan will be to test the instrument on 15 patients at the decision point. Based on feedback, the instrument will be modified accordingly before entering the final stage of evaluation (i.e., randomized trial).

Chemotherapy Decision Boards – Consistent with our overall plan, the node-positive and node-negative instruments will be tested in the clinic on a similar number of clinicians and patients. Field testing and preliminary analysis will be completed within the next six months. Our intention will be to present the computerized versions and results of feasibility testing at the upcoming “Era of Hope” meeting in Atlanta in June, 2000.

Significant progress has been made in reaching our first-year milestones as outlined in our Statement of Work. However, the study is slightly behind schedule due to a number of events. First, recruiting the research coordinator with required qualifications for this study was more protracted than anticipated. For the position of coordinator, we required an individual with skills in both qualitative and quantitative research, and a sound working knowledge of breast cancer. The

qualified incumbent was not available until December of 1998, and then only on a half-time basis until previous commitments were cleared up. In view of the caliber and previous experience of the individual, investigators deemed it appropriate to accommodate this interruption. Since March 1999, the incumbent has been working in the position on a full-time capacity, and significant progress has been made. Second, it was deemed appropriate that a more efficient way to proceed would be to develop the instruments in a sequential fashion rather than concurrently. This was felt to be more appropriate as lessons learned from one instrument could be applied to the next. It was decided to first develop the surgery instrument followed by the node-positive instrument followed by the node-negative instrument. This would appear to be a useful strategy. Lessons have been learned with the development of the first instrument that can now be more easily applied to the second instrument. It is anticipated that by the time the third instrument is developed, we will have gained sufficient expertise that this process will be expedited. Third, a randomized trial evaluating the standard node-negative chemotherapy instrument was delayed due to slow accrual. Research results from this ongoing trial will be important for the development of the computerized version. Delaying the development of this instrument until this information is available (mid December, 1999) will allow us to incorporate the research findings from the ongoing study.

Key Research Accomplishments

- Completed a review of the literature and updated the standard version of the surgery Decision Board.
- Completed a review of the literature and updated the standard version of the node-negative Decision Board.
- Completed a review of the literature and updated the standard version of node-positive Decision Board.
- Developed the computerized version of the surgical Decision Board.
- Initiating feasibility study of computerized version of surgery Decision Board.

Reportable Outcomes

Surgical Decision Board

- Standard version (updated)
- Computerized version (developed)

Node-Positive Decision Board

- Standard version (updated)
- Computerized version (completing development)

Node-Negative Decision Board

- Standard version (updated)

PUBLICATIONS

Whelan T, Gafni A, Charles C. Lessons learned from the Decision Board: A unique and evolving decision aid. Accepted for publication in Health Expectations, 1999.

Whelan T, Levine M, Gafni A, Sanders K, Willan A, Mirsky D, Schnider D, McCreedy D, Reid S, Kobylecky A, Reed K. Mastectomy or lumpectomy? Helping women make informed choices. Journal of Clinical Oncology, 1999; 17:1727-1735.

Irwin E, Arnold A, Whelan TJ, Reyno LM, Cranton P. Offering a choice between two adjuvant chemotherapy regimens: A pilot study to develop a decision aid for women with breast cancer. Patient Education and Counselling 1999; 37:283-291.

PRESENTATIONS

Whelan T, Levine M, Gafni A, Sanders K, Willan A, Mirsky D, Schnider D, McCreedy D, Reid S, Kobylecky A, Reed K. Mastectomy or lumpectomy? Helping women make informed choices. The Canadian Breast Cancer Research Initiative (CBCRI) "Reasons for Hope" National Scientific Conference, Toronto, June 17-19, 1999.

Whelan T. The Use of Decision Boards in Oncology. The 12th Centre for Health Economics and Policy Analysis Conference (CHEPA) "Treatment Decision-Making in the Clinical Encounter", McMaster University, Hamilton, ON, May 19-21, 1999.

Whelan, T. Decision Aids in Oncology. Cancer Care Quality of Life and Outcomes Symposium, Chicago, IL November 13-15, 1998.

FUNDING

Based on the favorable experience with the surgery Decision Board in the community, investigators have made an application to identify and develop other innovative approaches to disseminating clinical practice guidelines to physicians and cancer patients.

Whelan TJ, Charles CA, Levine MN, Sanders K, Graham ID, Sawka CA, Mirsky DJ, Browman G, Julian JA, Lewis MJ, Edge SB. Development of dissemination/ implementation strategies for clinical practice guidelines in breast cancer. Submitted to the U.S. Army Medical & Material Command, \$242,184, 2000-2002.

Conclusions

Important information has been gleaned from our evaluations of current instruments, e.g., surgery Decision Board and node-positive chemotherapy Decision Board. This information is being incorporated in the current computerized versions. Information from recent reviews of the literature reviews is also being incorporated in the new versions. Input from the focus groups with patients and physicians has been particularly helpful in designing these instruments. A computerized version of the surgery Board has been designed and is currently undergoing feasibility testing. The computerized version of the node-positive chemotherapy Board is nearing completion. Preliminary feedback from patients and surgeons has been extremely supportive. Surgeons have been impressed with the versatility of the instrument and ease of access. Patients have been impressed by the technology and depth of information obtained. A unique observation is that by using a laptop together, surgeons and patients sit together to explore the information. This adds another unexpected level of interaction between the physician and patient. The impact of the instrument on the physician-patient relationship will need to be evaluated.

References

1. Whelan T, Levine M, Gafni A, Sanders K, Willan A, Mirsky D, Schnider D, McCreedy D, Reid S, Kobylecky A, Reed K. Mastectomy or lumpectomy? Helping women make informed choices. *Journal of Clinical Oncology*, 1999; 17:1727-1735.
2. Sandrick K. Physicians study tool to help patients select treatment for breast cancer. *Bulletin of the American College of Surgeons* 1999, 84:24-28.
3. Whelan TJ, Sanders K, Reid S, Mirsky D, Levine M, Gafni A, Willan A, Lewis MJ. Evaluation of an instrument to aid in decision making for breast cancer surgery. Canadian Breast Cancer Research Initiative, NCIC, \$153,053, 1998-2000.
4. Levine MN, Gafni A, Markham B, MacFarlane D. A bedside decision instrument to elicit a patient's preference concerning adjuvant chemotherapy for breast cancer. *Annals of Internal Medicine* 1992; 117:53-58.
5. Fisher B, Dignam J, Wolmark N, DeCillis A, Emir B, Wickerham DL, Bryant J, Dimitrov NV, Abramson N, Atkins JN, Shibata H, Deschenes L, Marolese RG. Tamoxifen and chemotherapy for lymph node-negative, estrogen receptor positive breast cancer. *J Natl Cancer Inst* 1997; 89:1673-1682.
6. Whelan TJ, Sawka C, Levine M, O'Connor A, Gafni A, Reyno L, Willan A, Pritchard K. A randomized trial of a decision aid for the use of adjuvant chemotherapy in women with node-negative breast cancer. Canadian Breast Cancer Research Initiative, NCIC, \$142,338, 1995-1997.
7. Irwin E, Arnold A, Whelan TJ, Reyno L, Cranton P. Offering a choice between two adjuvant chemotherapy regimens: A pilot study to develop a decision aid for women with breast cancer. *Patient Education and Counselling* 1999, 37:283-291.
8. Levine MN, Bramwell VH, Pritchard KI, Norris BD, Shepherd LE, Abu-Zahra H, Findlay B, Warr D, Bowman D, Myles J, Arnold A, Vandenberg T, MacKenzie R, Robert J, Ottaway J, Burnell M, Williams CK, Tu D for the National Cancer Institute of Canada Clinical Trials Group. Randomized trial of intensive cyclophosphamide, epirubicin and fluorouracil chemotherapy compared with cyclophosphamide, methotrexate and fluorouracil in premenopausal women with node-positive breast cancer. *Journal of Clinical Oncology* 16:2651-2658, 1998.
9. Demetri GD, Berry D, Norton L, Broadwater G, Robert NJ, Duggan D, Henderson IC. Clinical outcomes of node-positive breast cancer patients treated with dose-intensified Adriamycin/cyclophosphamide (AC) followed by Taxol (T) as adjuvant systemic chemotherapy (CALGB 9141).

10. Bonadonna G, Valagussa P, Moliterni A, Zambetti M, Brambilla C. Adjuvant cyclophosphamide, methotrexate, and fluorouracil in node-positive breast cancer. *NEJM* 1995, 332:901-906
11. Fisher B, Brown AM, Dimitrov NV, Poisson R, Redmond C, Margolese RG, Bowman D, Wolmark N, Wsickerham DL, Kardinal CG, Shibata H, Paterons AHG, Sutherland CM, Robert NJ, Ager PJ, Levy L, Wolter J, Wozniak T, Fisher ER, Deutsch M. Two months of Doxorubicin-Cyclophosphamide with and without interval reinduction therapy compared with 6 months of cyclophosphamide, methotrexate and fluorouracil in positive-node breast cancer patients with Tamoxifen-nonresponsive tumors: Results from the National Surgical Adjuvant Breast and Bowel Project B-15. *J Clin Oncol* 1990, 8:1483-1496.
12. Early Breast Cancer Trialists' Collaborative Group. Tamoxifen for early breast cancer: an overview of the randomised trials. *The Lancet* 351:1451-1467, 1998.

Appendices

- Appendix 1: Whelan T, Levine M, Gafni A, Sanders K, Willan A, Mirsky D, Schnider D, McCready D, Reid S, Kobylecky A, Reed K. Mastectomy or Lumpectomy? Helping Women Make Informed Choices. *J Clin Oncol* 1999; 17:1727-1735.
- Appendix 2: Sandrick K. Physicians study tool to help patients select treatment for breast cancer. *Bulletin of the American College of Surgeons* 1999, 84:24-28.
- Appendix 3: Sample of Community Surgeon Letters
- Appendix 4: Copies of Node-negative Instruments: 3 Risk Categories
- Appendix 5: Irwin E, Arnold A, Whelan TJ, Reyno LM, Cranton P. Offering a choice between two adjuvant chemotherapy regimens: A pilot study to develop a decision aid for women with breast cancer. *Patient Education and Counselling* 1999; 37:283-291.
- Appendix 6: Panels from Node-positive Instrument
- Appendix 7: Panels from Surgery instrument

Appendix 1: Whelan T, Levine M, Gafni A, Sanders K, Willan A, Mirsky D, Schnider D, McCreedy D, Reid S, Kobylecky A, Reed K. Mastectomy or Lumpectomy? Helping Women Make Informed Choices. J Clin Oncol 1999; 17:1727-1735.

Mastectomy or Lumpectomy? Helping Women Make Informed Choices

By Timothy Whelan, Mark Levine, Amiram Gafni, Kenneth Sanders, Andrew Willan, Douglas Mirsky, Denise Schnider, David McCready, Susan Reid, Anna Kobylecky, and Kenneth Reed

Purpose: To develop an instrument to help clinicians inform their patients about surgical treatment options for the treatment of breast cancer and to evaluate the impact of the instrument on the clinical encounter.

Methods: We developed an instrument, called the Decision Board, to present information regarding the benefits and risks of breast-conserving therapy (lumpectomy plus radiation therapy) and mastectomy to women with early-stage breast cancer to enable them to express a preference for the type of surgery. Seven surgeons from different communities in Ontario administered the instrument to women with newly diagnosed clinical stage I or II breast cancer over an 18-month period. Patients and surgeons were interviewed regarding acceptability of the instrument. The rates of breast-conserving surgery performed by surgeons before and after the introduction of the instrument were compared.

Results: The Decision Board was administered to 175 patients; 98% reported that the Decision Board was easy to understand, and 81% indicated that it helped them make a decision. The average score on a true/false test of comprehension was 11.8 of 14 (84%) (range, 6 to 14). Surgeons found the Decision Board to be helpful in presenting information to patients in 91% of consultations. The rate of breast-conserving surgery decreased when the Decision Board was introduced (88% v 73%, $P = .001$)

Conclusion: The Decision Board is a simple method to improve communication and facilitate shared decision making. It was well accepted by patients and surgeons and easily applied in the community.

J Clin Oncol 17:1727-1735. © 1999 by American Society of Clinical Oncology.

RANDOMIZED TRIALS comparing mastectomy to breast-conserving therapy (lumpectomy plus radiation therapy) have demonstrated equivalent survival.¹⁻⁷ Thus the choice of treatment must be made on the basis of issues relating to quality of life, eg, the loss of the breast and potential effects on body image and sexuality versus an additional 5 to 7 weeks of radiation therapy with its associated side effects. Recent studies of clinical practice have shown wide geographic variation in the type of breast cancer surgery performed in North America and Europe.⁸⁻¹¹ Geographic variation in treatment practice may result from disease, institutional, practitioner, and patient-specific factors.¹² Studies suggest that the variability observed in the type of breast cancer surgery performed is unlikely to be fully explained by disease factors (such as extent of cancer) or institutional factors (such as access to radiation therapy).⁸⁻¹⁶ Other research had identified problems with communication of information between physicians and cancer patients.^{13,14} There remains concern that patients may not be fully informed regarding their treatment alternatives and/or may be overly influenced by the preference of their physician.^{8,15}

In the past, physicians often tended to make decisions for patients with little patient input.^{16,17} More recently, patients with cancer have indicated a need for more information about their disease and a desire to be involved in decisions about their care.^{18,19} This has been particularly true for women with breast cancer.²⁰ Shared treatment decision making involves providing information to patients on the

benefits and risks associated with different treatment alternatives and incorporating patients' values in the treatment decision.²¹

The Decision Board was developed to facilitate communication of information to cancer patients and enhance their ability to express a treatment preference.²² The Decision Board, a visual aid administered by the health professional, presents written and graphical information from randomized trials to patients regarding their treatment options.²³⁻²⁵ Previous studies have suggested that the instrument increases patient comprehension and empowers patients in the decision-making process.²³ A Decision Board that presents information regarding the benefits and risks of mastectomy

From the Supportive Cancer Care Research Unit and Departments of Medicine, Clinical Epidemiology and Biostatistics, and Surgery, McMaster University, Hamilton; Hamilton Regional Cancer Centre, Hamilton; Henderson Division, Hamilton Health Sciences Corporation, Hamilton; Ottawa Civic Hospital, Ottawa; Brantford General Hospital, Brantford; Department of Surgery, University of Toronto, Toronto; St. Catharines General Hospital, St. Catharines; and Guelph General Hospital, Guelph, Ontario, Canada.

Submitted October 5, 1998; accepted February 1, 1999.

Supported by the Canadian Breast Cancer Research Initiative, and a Health System Linked Research Grant (no. 04171) from the Ontario Ministry of Health.

Address reprint requests to Timothy J. Whelan, BM, BCh, MSc, c/o Hamilton Regional Cancer Centre, 699 Concession St, Hamilton, ON L8V 5C2 Canada; email tim_whelan@hrcc.on.ca.

© 1999 by American Society of Clinical Oncology.
0732-183X/99/1706-1727

and breast-conserving therapy to women with early breast cancer in a standardized and unbiased fashion may improve information transfer and enable patients to express a preference for the type of surgery performed.

Most breast cancer surgery is performed by general surgeons in community settings. Previous Decision Boards have been developed for patients and their oncologists in tertiary cancer centers. In this article, we describe the development of a Decision Board for patients and their surgeons in the community regarding the choice of surgical treatment for breast cancer. The results in terms of the acceptability and feasibility of the Board are reported. We also examine the rate of breast-conserving surgery performed before and after the use of the Decision Board in the community.

METHODS

Instrument Development

To develop the surgical Decision Board, we used methodology previously described.²²⁻²⁵ A systematic review of the literature was performed for studies comparing mastectomy and lumpectomy plus radiation for outcomes regarding survival, recurrence, and quality of life. We identified six randomized trials, one meta-analysis, 19 studies comparing the quality of life of the two different treatment approaches, and one systematic review.^{1-7,26-45} Individual interviews were held with two community surgeons and five women with breast cancer to identify important informational needs for decision making about breast cancer surgery.

After the literature review and interviews, two focus groups were assembled to identify the main characteristics of an effective decision aid. The first group included five patients and the second group included five general surgeons. Before the meetings, each participant was provided with background information regarding the two treatment options, the side effects associated with each treatment, and the effects of each treatment on recurrence, survival, and quality of life. The groups discussed and proposed information to be included in the decision aid. The main recommendations from the patient group were to include information regarding breast reconstruction, to provide a visual representation of the breast after mastectomy and breast-conserving therapy, and to provide a separate discussion of the potential effects of treatment on day-to-day living, body image, and sexuality. The surgeons recommended providing more detailed information about the side effects of surgery and radiation therapy. Based on these recommendations, scenarios were developed regarding the following: background information (about the disease and the purpose of the decision instrument); the two treatment options, mastectomy and lumpectomy plus radiation; the acute and long-term side effects associated with each treatment; and the effects of each treatment on the patient's breast, long-term survival, and quality of life. A prototype visual aid was constructed to present the information in an efficient and standardized manner. The instrument was then presented to the focus groups for review of content and clarity. Refinements were made based on feedback. The Decision Board was then piloted with two community surgeons and three patients at the decision point. Based on their responses, minor revisions were made.

The Decision Board is composed of laminated foam core and measures 25 inches wide by 20 inches high (Fig 1). It is large enough to permit the patient to read the display, but not so large or heavy to be cumbersome to store or carry. The board has four subtitles: Treatment Choice, Side Effects, Results of Treatment Choice for the Breast and Results of Treatment Choice for Survival. Below each heading are two informational panels (one for mastectomy and one for lumpectomy plus radiation) resulting in eight separate panels. The instrument is administered by the surgeon. Initially, each panel is covered by a sliding door. The panels are opened to reveal information in a sequential fashion. Each panel is read together by the patient and the surgeon. The patient is encouraged to ask questions during the presentation and afterward. At the end of the presentation, the patient is faced with an overall visual representation of her two options and the possible outcomes associated with each choice. In addition to the board, there are two separate informational cards, one is to be read before the presentation and discusses background information about breast cancer and the purpose of the board, and one is to be read after the presentation and asks the patient to reflect on how the treatment will affect her as an individual (see Appendix). An additional card providing further details regarding breast reconstruction is also made available. Upon completion of the Decision Board presentation, the patient is given a take-home version to review and discuss with others if she so desires.

The Decision Board was piloted with 30 healthy female volunteers to determine its validity and reliability. The instrument was administered on two occasions by a skilled interviewer. On the first occasion, the instrument was administered using standard information and the woman was asked to state her preference for mastectomy or lumpectomy plus radiation. Validity was then assessed by changing the information provided and determining whether preferences changed in a predictable manner. For example, if a woman chose lumpectomy plus radiation, information was then conveyed in which the difference in survival for lumpectomy plus radiation as compared with mastectomy was gradually decreased. It was predicted that if patients were told that there was a substantial decrease (20%) in survival associated with lumpectomy plus radiation, the majority of patients would choose mastectomy. For women who chose mastectomy, a similar but opposite approach was used. At the second visit, 3 to 4 weeks later, the instrument was readministered with standard information only and the patient was asked to state a preference.

The mean age of volunteers was 57.3 years; 17 (57%) were married and 16 (53%) had some postsecondary education. Thirty (100%) considered the Decision Board to be easy to understand and 24 (80%) found it helpful in making a decision. Twenty-nine (97%) volunteers recommended that it should be used for breast cancer patients. At first administration, 19 (63%) chose lumpectomy plus radiation and 11 (37%) chose mastectomy. In women who chose lumpectomy plus radiation, 17 (89%) switched preference when survival was decreased. For those women who chose mastectomy, nine (82%) switched preference when survival was reduced. Women's responses were stable over time. On readministration of the instrument 3 to 4 weeks later, 28 (93%) had the same preference (kappa statistic = 0.86).

Evaluation

After the Decision Board was assessed for validity and reliability in volunteers, it was then evaluated in the clinical practice setting. Seven surgeons from different communities in Ontario (Hamilton, Brantford, Guelph, St. Catharines, Toronto, and Ottawa) were instructed on the use

DECISION BOARD

TREATMENT CHOICE	SIDE EFFECTS	RESULTS OF TREATMENT CHOICE For Breast For Survival
MASTECTOMY <i>(Surgical Removal of the Breast)</i> <ul style="list-style-type: none"> • Entire breast will be removed • Some lymph nodes under your arm will be removed • You are left with a healing scar that runs across your chest • A drain is inserted near the scar under the arm, for 5-10 days, to remove excess fluid • After surgery, you may be referred to the Cancer Centre for consideration of other treatments (hormonal therapy or chemotherapy) • Radiation is not normally required 	MASTECTOMY <i>OFTEN</i> <ul style="list-style-type: none"> • Numbness and discomfort on the inside of the arm where nerves were cut • Pain, discomfort or numbness of the chest <i>SOMETIMES</i> <ul style="list-style-type: none"> • Stiffness of the shoulder • Collection of fluid in the scar that may need to be drained <i>RARELY</i> <ul style="list-style-type: none"> • Infection • Arm swelling 	MASTECTOMY • Healed scar across your chest • Some women may be upset by the loss of their breast • A breast prosthesis or breast form can be fitted • A breast can be reconstructed using plastic surgery • Cancer may come back on the chest. About 5 to 10 out of 100 women will experience this in the next 10 years • Cancer that comes back on the chest is usually treated by surgery, radiation, or both
LUMPECTOMY <i>(Surgical Removal of the Cancerous Lump)</i> <ul style="list-style-type: none"> • Only the cancerous lump and some surrounding tissue will be removed • Some of the lymph nodes under your arm will be removed • You are left with two healing scars, one on the breast and one under the arm • Often, a drain is inserted near the scar under the arm, for 5-10 days, to remove excess fluid • In some instances (in about 1 out of 10 women), all the cancer in the breast may not be removed and you may require further surgery • Once the breast has healed, 3-4 weeks after surgery, you will be referred to the Cancer Centre for consideration of radiation PLUS RADIATION <i>(X-ray Treatment)</i> <ul style="list-style-type: none"> • You will need to come to the Cancer Centre for planning of the radiation and for treatments • Your treatments will be daily for 5 weeks, excluding weekends • Each visit lasts approximately 30 to 45 minutes • The time between your surgery and the beginning of your radiation treatments may be 6-12 weeks • Other treatments (hormonal therapy and chemotherapy) may be considered • If you are treated with chemotherapy, your radiation will begin after chemotherapy 	LUMPECTOMY <i>OFTEN</i> <ul style="list-style-type: none"> • Numbness and discomfort on the inside of the arm where nerves were cut • Pain or discomfort of the breast <i>SOMETIMES</i> <ul style="list-style-type: none"> • Stiffness of the shoulder • Collection of fluid in the scar that may need to be drained <i>RARELY</i> <ul style="list-style-type: none"> • Infection • Arm swelling PLUS RADIATION <i>OFTEN</i> <ul style="list-style-type: none"> • Redness of the skin like a sunburn <i>SOMETIMES</i> <ul style="list-style-type: none"> • Increased firmness • Slight increase in the size of the breast • Slight increase in firmness of the breast <i>RARELY</i> <ul style="list-style-type: none"> • Blood vessels may become visible on small areas of the skin • Pneumonia 	LUMPECTOMY PLUS RADIATION • Two healed scars, one on the breast and one under the arm • Some indentation where the lump was removed or thickening of the breast tissue • Some women may be upset by the way the breast looks, but most (8 out of 10) are satisfied • Cancer may come back in the breast. About 5 to 10 out of 100 women will experience this in the next 10 years • Cancer that comes back in the breast is usually removed by further surgery (lumpectomy or mastectomy). Radiation cannot be given again.
		LUMPECTOMY PLUS RADIATION Your chance of surviving cancer is the SAME as with Mastectomy

Fig 1. The Decision Board.

of the decision aid. Five surgeons worked in community practices and two worked in university teaching hospitals. The surgeons were asked to approach all eligible patients attending their offices. To be eligible for this study, a woman had to have a recently diagnosed clinical stage I or II adenocarcinoma of the breast confirmed either by cytology or pathologic examination. Reasons for exclusion included medical contraindications to breast-conserving therapy, such as tumor too large or breast of insufficient size to permit a lumpectomy (defined as surgical excision of the tumor with a rim of normal tissue); multicentric carcinoma; diffusely abnormal mammographic changes; or serious comorbidity (eg, cardiovascular, respiratory) that would preclude definitive treatment; not otherwise a candidate for breast irradiation (eg, previous breast irradiation, pregnancy); inability to speak or read English fluently; or any psychiatric disorder that would preclude taking part in the process of shared decision making. The study protocol was reviewed and approved by the Hamilton Civics Hospital Institutional Review Board and informed consent to participate in the study was obtained from all patients.

All potentially eligible patients were identified by participating surgeons. Patients were recruited over an 18-month period from June 1996 to November 1997. Patients who met exclusion criteria were logged but were not approached to participate in the study. Consenting eligible patients were administered the Decision Board. A decision regarding treatment was made either at that visit or a few days later and surgery was scheduled. Patients were then interviewed by telephone by a skilled research assistant within 1 to 2 weeks. During the interview, which took 30 to 40 minutes to administer, patients were questioned regarding background demographic variables, preferences for involvement in decision making, general acceptability of the decision aid, comprehension of basic information relevant to decision making, satisfaction with information received and the decision-making process, other aspects regarding decision making (eg, Did they perceive a choice? Did the surgeon make a recommendation?), and their final treatment decision.

Patient preference for decision making was assessed using a 6-point Likert scale modeled on an instrument developed by Degner et al⁴⁶: 1 = "I prefer to make the final decision about which treatment I receive;" 2 = "I prefer to make the final selection of my treatment after seriously considering my doctor's opinion;" 3 = "I prefer that my doctor and I share responsibility for deciding which treatment is best for me;" 4 = "I prefer that my doctor makes the final decision about which treatment will be used, but seriously considers my opinion;" 5 = "I prefer to leave all decisions regarding my treatment to my doctor;" and 6 = "I am unsure." General acceptability of the decision aid was assessed by asking patients questions about how well they understood the Decision Board, its usefulness in helping them make a decision, its usefulness in helping them to think of questions to ask, and whether they would recommend it for others. Patient comprehension was assessed by correct responses to 14 statements that covered various content areas (description of options, side effects, and outcomes) using a "true, false, or unsure" type of format. Patient satisfaction with information received and decision-making was assessed using a 5-point Likert scale from 1 (Strongly Agree) to 5 (Strongly Disagree).

Surgeons were asked to complete a self-administered questionnaire after administration of the instrument for each patient. The questionnaire included items regarding the process of decision making, and acceptability and satisfaction with the decision aid. Administration of the instrument was also timed on a sample of patients ($n = 20$).

In an effort to determine if the introduction of the Decision Board influenced clinical practice in terms of the type of surgery performed, we reviewed the charts of all newly diagnosed stage I or II patients seen

by each surgeon for an 18-month period before the introduction of the Decision Board. Similar exclusion criteria as used for patients in the Decision Board cohort were applied. Age, marital status, clinical stage, and type of surgery performed were abstracted for all eligible patients. Patients seen for the two time periods before and after the introduction of the Decision Board were compared.

Statistical Analysis

Descriptive statistics were generated for the demographic characteristics and the outcome variables. Patients' responses for preferences for decision making and acceptability of the decision aid are reported as frequencies. Patient comprehension was assessed by determining the number of correct responses over the total number of statements. For responses to items regarding satisfaction with information received and the decision-making process, patients who responded 1 (Strongly Agree) or 2 (Agree) on a 5-point Likert scale were identified as satisfied. Similarly, surgeons who reported 1 (Strongly Agree) or 2 (Agree) to the statement "I was satisfied with the decision-making process" were identified as satisfied. To determine if physician satisfaction with the Decision Board was related to their use of the instrument, average satisfaction with decision making was calculated for each surgeon and correlated with the number of times the board was used by a particular physician using a Pearson correlation.

In an effort to determine if any factors (eg, physician or patient characteristics) predicted a patient's choice for surgery, a multivariate logistic regression analysis was performed. Variables examined in the model included patient's age, marital status, level of education, dependent children, socioeconomic status, distance from the nearest radiation therapy facility, clinical stage, surgeon seen, gender of the surgeon, surgeon's recommendation, and recommendation from the spouse or first-degree relative.

Patients seen before and after the introduction of the Decision Board were compared with respect to demographic characteristics and disease stage using contingency χ^2 tests. The rates of breast-conserving surgery for the two time periods were compared with the χ^2 test.

RESULTS

Patient and Surgeon Characteristics

A total of 244 patients were initially screened for study eligibility; 65 were excluded by participating surgeons. Thirty-three patients were excluded because of medical contraindications (eg, technical factors [large tumor-to-breast ratio], multicentric carcinoma, diffusely abnormal mammogram, or comorbidity), 19 patients were excluded because of administrative issues (eg, non-English speaking, seen in hospital, or approached for another clinical trial), and 13 patients were excluded for other reasons (eg, a previous contralateral mastectomy or lumpectomy).

Of 179 patients identified as eligible, 175 agreed to presentation of the Decision Board. Four patients refused to use the Decision Board because they had already made a decision about treatment and did not want to discuss treatment options. The mean age of consenting patients was 56.2 years (range, 33 to 80 years). Seventy percent had high

school education or greater, 46% were employed outside the home, and 20% had dependent children. Other demographic and disease characteristics are listed in Table 1.

The mean age of the surgeons was 42.2 years (range, 36 to 50 years); three were female and two had an academic affiliation. The mean number of patients who were administered the Decision Board by each surgeon was 25 (range, nine to 74).

Decision-Making Process

The majority of patients (51%) preferred to make the final decision or share the decision with the surgeon (36%); 11% preferred that the doctor make the final decision after considering their opinion, and 1% preferred to leave the decision to the doctor. Ninety-eight percent of women reported that the Decision Board was easy to understand, 81% of patients indicated that the Decision Board helped them make a decision, 62% reported that it helped them think of questions to ask, and 64% ($n = 112$) showed it to someone else, most commonly their spouse ($n = 61$), first-degree relatives ($n = 48$), or friends ($n = 13$). Ninety-eight percent of patients recommended that the Decision Board should be used with other patients.

The average score on the true/false test of comprehension was 11.8 of 14 (84%) (range, 6 to 14). The proportion of correct responses for each statement was greater than 70% for all statements except for one relating to skin telangiectasia after breast irradiation postlumpectomy (Table 2). Ninety-seven percent of patients reported satisfaction with the information received, and 95% reported satisfaction with the decision-making process.

The Decision Board took an average of 21 minutes to administer. Surgeons reported being comfortable with the administration of the instrument (mean score of 89 on a linear analog scale from 1 to 100). Surgeons found the Decision Board helpful in presenting information to patients in 91% of consultations, and reported being satisfied with

Table 2. Patient Comprehension: Correct Responses by Statement Type ($N = 175$)

Statement Regarding	% Correct Response
Treatment Options	
Definition of mastectomy	100
Availability of breast reconstruction	92
Use of a breast prosthesis	98
Need for radiation postlumpectomy	99
Other treatments available (eg, chemotherapy)	94
Side effects	
Scar associated with mastectomy	98
Pain and numbness of the chest associated with mastectomy	77
Potential for breast deformity postlumpectomy	90
Erythema of skin associated with breast irradiation	91
Skin telangiectasia associated with breast irradiation	15
Subcutaneous fibrosis associated with breast irradiation	76
Outcomes	
Chest wall recurrence postmastectomy	89
Local breast recurrence after lumpectomy	72
Equivalent survival for mastectomy or lumpectomy	95

the decision-making process in 97% of consultations. Physician satisfaction did not correlate with the number of times the board was used ($P = 0.23$).

In most instances (57%), the patient's decision was made during the consultation. In a minority of cases, the decision was made a couple of days after the consultation (32%) or before the consultation itself (11%). All but three patients perceived that they had been offered a clear choice regarding treatment options. Patients reported that surgeons made a recommendation in 39% of encounters. In most of these (78%), the patient had requested a recommendation. Forty-seven percent of patients sought advice from other individuals, including spouse ($n = 20$), other first-degree relatives ($n = 27$), friends ($n = 21$), or family doctor ($n = 19$). In all, 73% of patients chose lumpectomy and radiation, 26% chose mastectomy. (Two patients elected not to have any form of surgical treatment and chose alternative therapies instead.) On multivariate analysis, the only factor that predicted for a patient's choice was the surgeon's recommendation for the type of surgery ($P = .0001$).

Two hundred thirty-nine patients underwent surgery in the practice during the 18 months before the introduction of the Decision Board. Forty-five were excluded: 26 because of medical contraindications, nine because of administrative issues, and 10 for other reasons. The remaining 194 patients were compared with 175 patients who were administered the Decision Board. Both groups were comparable with respect to marital status, age, and stage of disease (Table 1). Breast-conserving surgery was performed more commonly before the introduction of the Decision Board (170 of 194 [88%] v 127 of 175 [73%], $P = .001$).

Table 1. Characteristics of Patients

	Decision Board Use				P
	Before (n = 194)		After (n = 175)		
	No.	%	No.	%	
Marital Status					
Married/cohabiting	135	70	121	69	.93
Single/divorced/widowed	59	30	54	31	
Age, years					
≤ 60	104	54	109	62	.09
> 60	90	46	66	38	
Clinical Stage					
I	125	64	113	65	.98
II	69	36	62	35	

DISCUSSION

For women with early breast cancer, the decision regarding the optimal form of surgical treatment is not straightforward. We developed a Decision Board to help surgeons present information regarding the benefits and risks of the two treatment options to women diagnosed with early breast cancer to enable them to express a preference for treatment.

Previous Decision Boards regarding the choice of adjuvant therapies were developed in a tertiary cancer center.²²⁻²⁵ Instruments were targeted primarily to younger women 4 to 6 weeks after their initial diagnosis and were administered by academic oncologists or primary care nurses. The Decision Board for breast cancer surgery was a departure from previous work. It was introduced to women of all age groups shortly after their diagnosis and administered by general surgeons in the community.

The surgical Decision Board seemed to be well accepted by patients and surgeons alike. The majority of patients indicated a desire to be involved in decision making in a manner that is consistent with that of previous studies of women with breast cancer,²⁰ and almost all patients who were approached agreed to administration of the instrument. Comprehension of information was very good. The majority of patients who used the Decision Board were very satisfied with the information exchanged and the decision-making process. Almost all patients felt they were offered a clear choice. Surgeons also reported similar high satisfaction and comfort with administration of the instrument. The board took on average only 20 minutes to administer and did not seem to unduly lengthen the consultation. These results are consistent with our previous experience with such instruments in tertiary cancer centers.

In the regression analysis, the only variable that independently predicted choice was the surgeon's recommendation for either lumpectomy or mastectomy. In most of these cases, the patients had requested a recommendation. These results suggest that patients' preferences cannot be predicted *a priori* and support the use of the Decision Board to incorporate patients' preferences in difficult treatment decisions.

The impact of the Decision Board on treatment practice was evaluated using a before/after design. The rate of breast-conserving surgery decreased (with a corresponding increase in the use of mastectomy) after the introduction of the Decision Board. Surgeons participating in the study performed breast-conserving surgery relatively commonly before the introduction of the Decision Board. When women were offered a choice of treatment with the use of the Decision Board, breast-conserving surgery was performed

less often. Many of these women supported their decision by indicating that they wanted to avoid radiation therapy and were less concerned about body image.

The observed results were unexpected. It is unclear whether these results are due to the use of the Decision Board or the nature of our study design (before/after). It might be expected that in certain circumstances the Decision Board would affect a patient's choice, such as when patients are not clearly informed of their different treatment options, when detailed information regarding the different treatment options and associated outcomes are not provided, or when patients are not actively involved in the decision-making process. One or all of these reasons may have explained the results observed in our study. Before introduction of the Decision Board, surgeons may not have clearly offered the different treatment options of mastectomy or lumpectomy. Additionally, details regarding the need for radiation treatment after lumpectomy and the risk of recurrence of cancer in the breast may not have been routinely presented. Finally, before the use of the Decision Board, patients' preferences may not have been routinely elicited. The ideal design to evaluate the impact of the Decision Board is a randomized controlled trial. This type of design was beyond the scope of the present study. Furthermore, a randomized controlled trial is not without its own methodologic problems. In a randomized trial, surgeons using the Decision Board may tend to adopt this approach (or a similar one) in standard practice, leading to the problem of contamination. A larger study in which surgeons are randomized to use the instrument or not may avoid this problem. The design we chose also circumvented this concern, but was at potential risk of bias due to confounding changes in patterns of practice over time. To avoid this, we evaluated all eligible patients over two consecutive relatively short periods of time.

An important attribute of the Decision Board is that it can be easily modified to incorporate local variations in practice or changes to treatment approaches over time. Recently published randomized trials suggest a survival benefit for locoregional radiation therapy after mastectomy in women with node-positive breast cancer treated with systemic therapy.^{47,48} Based on the results of these studies, it is anticipated that locoregional radiation therapy will be offered more frequently to women at high risk of locoregional recurrence. This adds to the complexity of the treatment decision-making process. However, usually there is a sequence of treatment decisions for early-stage breast cancer. The decision for locoregional radiation is most often made by the patient and her oncologist after surgery when important pathologic information is available. In addition, many women will have node-negative breast cancer, and the

use of locoregional radiation therapy postmastectomy is unlikely to be an option. A brief discussion of the use of locoregional radiation therapy after mastectomy treatment could be included in the surgical decision aid, but for the majority of women, this decision is likely to be best made after surgery.

Various types of decision aids have been developed to facilitate communication of information to patients and elicit their treatment preferences. Aside from decisional analysis,⁴⁹ which is an indirect method for eliciting patients' preferences for treatment, direct methods that involve the use of visual aids, audio tapes,⁵⁰ and computer technology⁵¹ have been advocated because they make few assumptions and are more easily administered. In trying to develop a decision aid for breast cancer surgery, we identified several criteria that we felt were important: (1) The instrument should encourage direct two-way communication in addi-

tion to information transfer. This was an important consideration. Patients have indicated that the choice of breast cancer surgery is an important decision, and relationship building seems to be an important component of shared decision making.²¹ (2) The instrument should not take too long to administer, and it should be inexpensive and easy to use. (3) The instrument should have been used previously with oncology patients. The Decision Board met these criteria. The surgical Decision Board was shown to facilitate shared decision making. It was well accepted by patients and surgeons and was easily applied in the community. These results support its wider use in clinical practice.

ACKNOWLEDGMENT

We thank Angela Frisina, Marguerite Neimanis, and Ann Fucic for their assistance with the development and design of the Decision Board and data collection for this study.

APPENDIX The Decision Board

Introduction: Breast cancer may be treated in a variety of ways, including surgery, radiation therapy, chemotherapy, and hormonal therapy. The first step in the treatment of breast cancer is to remove the cancer by surgery. Today we will discuss the two choices for surgical treatment. This is not a decision that I, as your doctor, can make alone. We feel it is important for you to understand a little bit about breast cancer so you can take part in deciding what is best for you.

Two types of surgery are possible: one is removal of the breast, called a mastectomy; the second is removal of the lump, called lumpectomy. Since the early 1980s, the results of medical studies have shown that the two treatments are the same for survival. In other words, one treatment is not better than the other for improving your chances of surviving cancer. The two treatments do differ, however. Mastectomy results in the loss of your breast, and usually no radiation therapy is required. Lumpectomy, on the other hand, involves removal of the part of the breast that contains the cancer, and in addition, radiation therapy is offered.

Both of these treatments also include an axillary node dissection. Some nodes or glands under the arm are removed at the time of surgery. This is done to see if the cancer has spread to these nodes. If cancer spreads to these nodes, there is a higher chance that the cancer may spread to other parts of the body. This is important information for you and your doctor to help to decide if other treatments, such as hormonal therapy or chemotherapy, are necessary.

Other Issues: We have discussed your choices for surgery, what that entails, the side effects, and possible outcomes. I have a copy of the information presented on the Decision Board for you to take home. In choosing between the two options, please read carefully and make sure that you understand what is available.

Remember, the chance for survival is the same for each choice. So in deciding between the two options, think about the issues that will affect your day-to-day life. Keep in mind that every woman is different and that you must choose the option that is best for you.

You may want to consider some of the following:

- How will the results of your treatment choice affect your daily activities, for example, the way you dress or the style of clothing you like to wear?
- How will the results of your treatment choice affect the way you feel about your self, your body, and your sexuality?
- How will the results of your treatment choice affect your relationships with others?
- Will the treatment you choose be inconvenient for you? Consider the length of the treatment and the need to travel to the cancer center.

Some women find it helpful to speak with other women who have been through a similar experience. If you would like to speak with another woman with breast cancer, this can be arranged.

REFERENCES

1. Veronesi U, Banfi A, Del Vecchio M, et al: Comparison of Halsted mastectomy with quadrantectomy, axillary dissection, and radiotherapy in early breast cancer: Long-term results. *Eur J Cancer Clin Oncol* 22:1085-1089, 1986
2. Fisher B, Redmond C, Poisson R, et al: Eight-year results of a randomized clinical trial comparing total mastectomy and lumpectomy with or without irradiation in the treatment of breast cancer. *N Engl J Med* 320:822-828, 1989

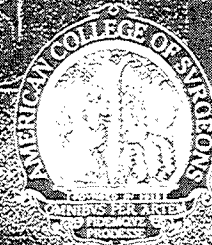
3. Sarrazin D, Lê MG, Arriagada R, et al: Ten-year results of a randomized trial comparing a conservative treatment to mastectomy in early breast cancer. *Radiother Oncol* 14:177-184, 1989
4. Blichert-Toft RC, Andersen JA, Overgaard M, et al: Danish randomized trial comparing breast conservation therapy with mastectomy: Six years of life-table analysis. *J Natl Cancer Inst Monographs* 11:19-25, 1992
5. Lichter AS, Lippman ME, Danforth DN, et al: Mastectomy versus breast-conserving therapy in the treatment of stage I and II carcinoma of the breast: A randomized trial at the National Cancer Institute. *J Clin Oncol* 10:976-983, 1992
6. van Dongen JA, Bartelink H, Fentiman IS, et al: Randomized clinical trial to assess the value of breast-conserving therapy in stage I and II breast cancer, EORTC 10801 Trial. *J Natl Cancer Inst Monogr* 11:15-18, 1992
7. Early Breast Cancer Trialists Collaborative Group: Effects of radiotherapy and surgery in early breast cancer: An overview of the randomized trials. *N Engl J Med* 333:1444-1455, 1995
8. Nattinger AB, Gottlieb MS, Veum J, et al: Geographic variation in the use of breast-conserving treatment for breast cancer. *N Engl J Med* 326:1102-1107, 1992
9. Farrow DC, Hunt WC, Samet M: Geographic variation in the treatment of localized breast cancer. *N Engl J Med* 326:1097-1101, 1992
10. Iscoe NA, Goel V, Wu K, et al: Variation in breast cancer surgery in Ontario. *Can Med Assoc J* 150:345-363, 1994
11. Grilli R, Scorpiglione N, Nicolucci A, et al: Variation in use of breast surgery and characteristics of hospitals' surgical staff. *Int J Qual Health Care* 6:233-238, 1994
12. Deber R, Thompson G: Variations in breast cancer treatment decisions and their impact in mounting trials. *Control Clin Trials* 11:353-372, 1990
13. MacKillop WJ, Stewart WE, Ginsburg AD, et al: Cancer patients' perceptions of their disease and its treatment. *Br J Cancer* 58:355-358, 1988
14. Siminoff LA, Fetting JH, Aeloff MD: Doctor-patient communication about breast cancer adjuvant therapy. *J Clin Oncol* 7:1192-1200, 1989
15. Margoese RG: Breast cancer surgery: Who chooses and how? *Can Med Assoc J* 150:331-333, 1994
16. Rose G: Reflections on the changing times. *BMJ* 301:683-687, 1990
17. Brock DW, Wartman SA: When competent patients make irrational choices. *N Engl J Med* 332:1595-1599, 1990
18. Cassileth BR, Zupkis RV, Sutton-Smith K, et al: Information and participation preferences among cancer patients. *Ann Intern Med* 92:832-836, 1980
19. Blanchard CG, Labrecque MS, Ruckdeschel JC, et al: Information and decision-making preferences of hospitalized adult cancer patients. *Soc Sci Med* 27:1139-1145, 1988
20. Degner LF, Kristjanson LJ, Bowman D, et al: The patient-physician relationship: Information needs and decisional preferences in women with breast cancer. *JAMA* 277:1485-1492, 1997
21. Charles C, Gafni A, Whelan T: Shared decision-making in the medical encounter: What does it mean? *Soc Sci Med* 44:681-692, 1997
22. Levine MN, Gafni A, Markham B, et al: A bedside decision instrument to elicit a patient's preference concerning adjuvant chemotherapy for breast cancer. *Ann Intern Med* 117:53-58, 1992
23. Whelan TJ, Levine MN, Gafni A, et al: Breast irradiation post-lumpectomy: Development and evaluation of a decision instrument. *J Clin Oncol* 13:847-853, 1995
24. Sebban C, Browman G, Gafni A, et al: Design and validation of a bedside instrument to elicit a patient's preference concerning allogeneic bone marrow transplantation in chronic myeloid leukemia. *Am J Hematol* 48:221-227, 1995
25. Elit L, Levine MN, Gafni A, et al: Patients' preferences for therapy in advanced epithelial ovarian cancer: Development, testing and application of a Bedside Decision Instrument. *Gynecol Oncol* 62:329-335, 1996
26. Maunsell E, Brisson J, Deschenes L: Psychological distress after initial treatment for breast cancer: A comparison of partial and total mastectomy. *J Clin Epidemiol* 42:765-771, 1989
27. Steinberg MD, Juliano MA, Wise L: Psychological outcome of lumpectomy versus mastectomy in the treatment of breast cancer. *Am J Psychiatry* 142:34-39, 1985
28. Lasry J-CM, Margoese RG, Poisson R, et al: Depression and body image following mastectomy and lumpectomy. *J Chron Dis* 40:529-534, 1987
29. Meyerowitz BE: Psychosocial correlates of breast cancer and its treatment. *Psychol Bull* 87:108-131, 1980
30. Ganz PA, Coscarelli Schag C, Polinsky ML, et al: Rehabilitation needs and breast cancer: The first month after primary therapy. *Br Cancer Res Treat* 10:243-253, 1987
31. Schain W, Edwards BK, Gorrell CR, et al: Psychosocial and physical outcomes of primary breast cancer therapy: Mastectomy vs excisional biopsy and irradiation. *Br Cancer Res Treat* 3:377-382, 1983
32. Beckmann J, Johansen L, Richardt C, et al: Psychological reactions in younger women operated on for breast cancer. *Dan Med Bull* 30:10-16, 1983
33. Wolberg WH, Romsaas EP, Tanner MA, et al: Psychosexual adaptation to breast cancer surgery. *Cancer* 63:1645-1655, 1989
34. Levy SM, Herberman RB, Lee JK, et al: Breast conservation versus mastectomy: Distress sequelae as a function of choice. *J Clin Oncol* 7:367-375, 1989
35. Eisenberg HS, Goldenberg IS: A measurement of quality of survival of breast cancer patients, in Hayward JL, Bulbrook RD (eds): *Clinical Evaluation of Breast Cancer*. San Diego, CA, Academic, 1966, pp 93-108
36. de Haes JCJM, van Oostrom MA, Welvaart K: The effect of radical and conserving surgery on the quality of life of early breast cancer patients. *Eur J Surg Oncol* 12:337-342, 1986
37. Sanger CK, Reznikoff M: A comparison of the psychological effects of breast-saving procedures with the modified radical mastectomy. *Cancer* 48:2341-2346, 1981
38. Kemeny MM, Wellisch DK, Schain WS: Psychosocial outcome in a randomized surgical trial for treatment of primary breast cancer. *Cancer* 62:1231-1237, 1988
39. Ashcroft JJ, Leinster SJ, Slade PD: Breast cancer: Patient choice of treatment—Preliminary communication. *J R Soc Med* 78:43-46, 1985
40. Taylor SE, Lichtman RR, Wood JV, et al: Illness-related and treatment-related factors in psychological adjustment to breast cancer. *Cancer* 55:2506-2513, 1985
41. Baider L, Rizel S, Kaplan De-Nour A: Comparison of couples' adjustment to lumpectomy and mastectomy. *Gen Hosp Psychiatry* 8:251-257, 1986

42. Holmberg L, Omne-Ontén M, Burns T, et al: Psychosocial adjustment after mastectomy and breast-conserving treatment. *Cancer* 64:969-974, 1989
43. Rotstein S, Nilsson B, Gustavson-Kadaka E, et al: Long-term follow-up of sickness periods in breast cancer patients primarily treated with surgery and radiotherapy or surgery only. *Acta Oncol* 28:817-822, 1989
44. Keibert GM, de Haes JCJM, van de Velde CJH: The impact of breast-conserving treatment and mastectomy on the quality of life of early-stage breast cancer patients: A review. *J Clin Oncol* 9:1059-1070, 1991
45. Ganz PA, Schag CA, Lee JJ, et al: Breast conservation versus mastectomy: Is there a difference in psychological adjustment or quality of life in the year after surgery. *Cancer* 69:1729-1738, 1992
46. Degner LF, Sloan JA: Decision making during serious illness: What role do patients really want to play? *J Clin Epidemiol* 45:941-950, 1992
47. Overgaard M, Hansen PS, Overgaard J, et al: Post-operative radiotherapy in high-risk premenopausal women with breast cancer who receive adjuvant chemotherapy: Danish Breast Cancer Cooperative Group 82b Trial. *N Engl J Med* 337:949-955, 1997
48. Ragaz J, Jackson SM, Le N, et al: Adjuvant radiotherapy and chemotherapy in node-positive premenopausal women with breast cancer. *N Engl J Med* 337:956-962, 1997
49. Pauker SG, Kassirer JP: Decision analysis. *N Engl J Med* 316:250-258, 1987
50. O'Connor AM, Tugwell P, Wells G: Testing a portable, self-administered, decision aid for post-menopausal women considering long-term hormone replacement therapy (HRT) to prevent osteoporosis and heart disease. *Med Decis Making* 14:414-438, 1994
51. Barry MJ, Fowler FJ, Mulley AG, et al: Patient reactions to a program designed to facilitate patient participation in treatment decisions for benign prostatic hyperplasia. *Med Care* 33:771-782, 1995

Appendix 2: Sandrick K. Physicians study tool to help patients select treatment for breast cancer. Bulletin of the American College of Surgeons 1999, 84:24-28.

BULLETIN

AMERICAN COLLEGE OF SURGEONS



September 1939
Volume 3, Number 3



Patient
Protection
Legislation

BULLETIN

AMERICAN COLLEGE OF SURGEONS



SEPTEMBER 1999
Volume 84, Number 9

FEATURES

- | | |
|--|-----------|
| A brief history on patient protection legislation
<i>Christian Shalgian</i> | 8 |
| <hr/> | |
| A radical change of direction: Part I
<i>Donald C. Mullen, MD, MDiv, FACS</i> | 13 |
| <hr/> | |
| Physicians study tool to help patients select treatment for breast cancer
<i>Karen Sandrick</i> | 24 |
| <hr/> | |
| In their own words:
A surgeon's perspective on the American Tort Reform Association's efforts to achieve medical liability reform
<i>Peter E. Petrucci, MD, FACS</i> | 29 |
| <hr/> | |
| ACS Officers and Regents | 32 |

DEPARTMENTS

- | | |
|---|-----------|
| The Board Report
<i>Y2K at the ACS</i>
<i>George F. Sheldon, MD, FACS</i> | 3 |
| <hr/> | |
| Dateline: Washington
<i>Washington Office,</i>
<i>Socioeconomic Affairs Department</i> | 6 |
| <hr/> | |
| The Journal page | 43 |

Stephen J. Regnier
Editor

Linn Meyer
Director of
Communications

Jennifer F. Herendeen
Senior Editor

Tina Woelke
Senior Production Editor

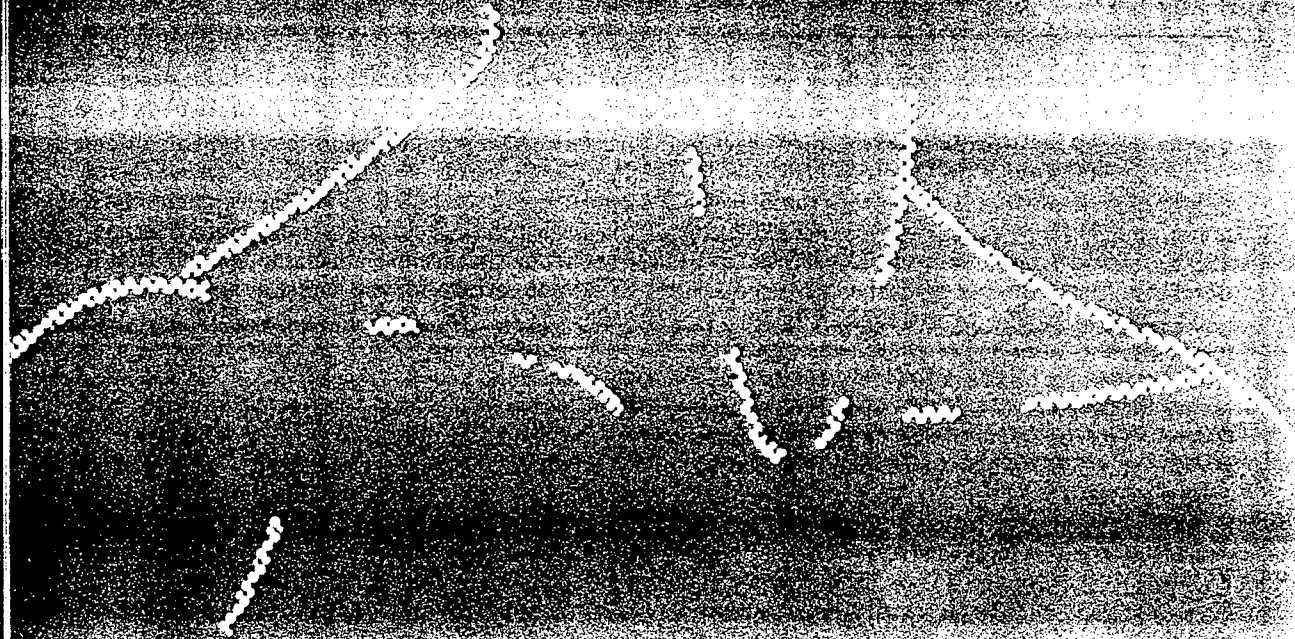
Other Brother Design
Front cover

About the cover...

Many questions pertaining to patient protection loom large on the health care horizon. Yet, as controversies continue as to who decides and provides what care patients receive, physicians, legislators, and others involved in health care look for an answer through legislation.

In "A brief history on patient protection legislation" (p. 8), Christian Shalgian of the ACS Washington Office tracks and discusses the history of patient care legislation, the Patient Bill of Rights, and comprehensive managed care reform legislation introduced in the 106th Congress.

According to Mr. Shalgian, "...the outlook for managed care reform remains uncertain, although it appears that Congress will spend a significant amount of time debating the tough questions involved."



to help patients select treatment for breast cancer

by Karen Sandrick, Chicago, IL



Women with Stage I or II breast adenocarcinoma face agonizing treatment choices. While their surgeons make it clear that breast-conserving surgery and mastectomy are equivalent in achieving long-term survival, the women still have to mull over the details of each treatment option—for example, the extent of surgery, nature and location of the incision, need for a drain, and use of other postoperative therapy. The women must compare the likelihood and type of side effects and weigh other outcomes, such as the appearance of the breast and the incision scar after surgery. These women also must consider highly individual issues and decide how the results of their choice of treatment will affect their self-esteem, body image, sexuality, personal relationships, and the way they dress or their style of clothing.

Many women with invasive breast cancer need to overcome misconceptions before they can wisely choose therapy. "Most of the patients and families who come to our breast center perceive a lumpectomy to be just that; they believe we will be taking out the lump with a minimal amount of breast tissue around it. They don't realize that we will be removing the malignancy with a substantial amount of normal breast tissue in order to get clear pathological margins; so they will be having more surgery than they expected," said Douglas Mirsky, MD, MSc, FACS, a general surgeon at Ottawa Civic Hospital, Ottawa, ON.

Nor are the women aware that they most likely will need radiotherapy after breast-conserving surgery or that there is a low but definite risk of local recurrence of cancer in the breast in spite of excellent surgery and radiotherapy. "They don't like the idea they may have to go through this whole terror again," Mirsky added.

Empowered patients

There are many types of educational vehicles for helping women sort through the various aspects of treatment for breast cancer, including computer-based programs and CD-ROMs, audiotapes, and pamphlets. However, these materials are given to women after they have met with and discussed their disease and treatment with the surgeon, and the instruments are not interactive. The materials were designed to impart or reinforce information, not to improve direct communication between

patients and their surgeon or allow women to participate in the decision-making process with their physician during the surgical consultation.

Mirsky, along with six other Canadian surgeons, recently tested an educational tool that facilitates the communication of information about breast conserving surgery and mastectomy, increases patients' comprehension of the risks and benefits of treatment, enhances the ability of patients to express their treatment preferences, and empowers their involvement in decision making. For Mirsky and his surgical colleagues, the tool reduces the amount of time needed to discuss breast cancer therapy, provides clear and concise comparisons, and yet permits surgeons to embellish and augment important aspects of treatment or follow-up care and clarify perceptions. "So patients are not leaving with their heads spinning," he said.

The Decision Board for mastectomy or lumpectomy is one of a series of decision aids involving breast cancer treatment alternatives that have been developed since the early 1990s when controversy surrounded the appropriateness of certain forms of treatment (such as adjuvant chemotherapy for node-negative breast cancer), and evidence started appearing in the literature that communication between physicians and cancer patients was poor.

Tailored information

A classic research paper in the *Journal of Clinical Oncology* in 1989 found that physicians tended to be unvarying in their presentation of information to women about breast cancer therapy. The information was not tailored to the woman, the stage of disease, size of the tumor, the risk of local or distant recurrence, or the prospects for survival.¹ "The physicians were not specific about associated benefits and risks. They tended to use qualitative information, saying things like: 'This will help you.' 'The outcome for this treatment is good.' 'The side effects are not bad,'" said radiation oncologist Timothy Whelan, BCh, MSc. "So when the researchers interviewed women afterward, not surprisingly, they found that the women had poor understanding of the associated benefits and risks of therapy. And when a physician made a rather firm recommendation about treatment, the patient generally accepted it," said Whelan, an associate professor in the department of medicine at



Dr. Ken Sanders, a general surgeon in Hamilton, ON, administering the Decision Board to a patient.

McMaster University, Toronto, and principal investigator in the development of the Decision Board.

Other research at the time indicated that cancer patients, especially women with breast cancer, wanted more information about their disease and more of a role in making decisions about their care.²⁻⁵

After creating a decision aid for counseling women with node negative breast cancer about adjuvant chemotherapy and irradiation after lumpectomy, Whelan and his associates at the Supportive Cancer Care Research Unit in Hamilton Regional Cancer Centre, Hamilton, ON, focused on breast conserving surgery and mastectomy because the choice between the two "is not clear cut,"

he said. "Choosing between lumpectomy and mastectomy can be looked upon as a difficult decision because clearly there is no difference in survival, but there is impact on quality of life," he said.

The objective was to create an educational instrument that would be evidence-based and yet inexpensive, easy to use for both physicians and patients, and easy to incorporate in the standard surgical consultation. Whelan and his associates consequently conducted a systematic review of the literature that compared mastectomy and breast conserving surgery plus radiotherapy and coalesced survival, recurrence, and quality of life data from six randomized trials, one meta-analysis, one systematic review, and 19 outcomes studies. The researchers also conducted interviews with sur-

geons and breast cancer patients to identify the types of information needed to choose between therapies; assembled focus groups of physicians and patients to refine the characteristics of an effective decision aid; and conducted a small pilot test with community surgeons and patients to fine-tune the instrument.

The result is a 20 x 25-inch Plexiglas card with a foam core that is large enough to display but small and light enough to carry and store. The board contains information about mastectomy and lumpectomy plus radiation in four separate panels: treatment choice, side effects, results of treatment for the breast, and results of treatment for survival. Information in each panel is presented as a series of succinct, bulleted items. The mastectomy panel, for example, explains that:

- the entire breast and some lymph nodes will be removed,
- the patient will be left with a scar running across the chest,
- a drain will be inserted near the scar under the arm and remain in place for 5 to 10 days after surgery to withdraw excess fluid,
- the patient may be referred for other hormonal or drug treatment after surgery,
- radiation normally is not needed.

The panel on side effects groups signs and symptoms by the likelihood of their occurrence: often, sometimes, or rarely. Information about the results of treatment for the breast is accompanied by an illustration of the way the breast will appear after surgery, and the final panel for each treatment option stresses that the chance of surviving cancer is the same regardless of whether the choice of treatment is mastectomy or breast conserving surgery.

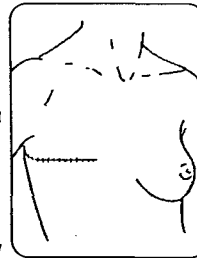
Each panel of the Decision Board is covered by a sliding door. During the consultation with the patient, the surgeon opens each panel in succession, and both the surgeon and the patient read the information that is revealed. The surgeon can then

RESULTS OF TREATMENT CHOICE For Breast

For Survival

MASTECTOMY

- Healed scar across your chest
- Some women may be upset by the loss of their breast
- A breast prosthesis or breast form can be fitted
- A breast can be reconstructed using plastic surgery
- Cancer may come back on the chest. About 5 to 10 out of 100 women will experience this in the next 10 years
- Cancer that comes back on the chest is usually treated by surgery, radiation, or both



MASTECTOMY
Your chance of surviving cancer is the SAME as with Lumpectomy plus Radiation

A segment of the Decision Board.

tailor the discussion to the patient's particular circumstances and answer the patient's questions.

Additional information cards also are available. The first, which is reviewed with the patient before using the Decision Board, provides a general explanation of surgical treatment for breast cancer, lists and defines each of the two types of surgical treatment but emphasizes that neither treatment is better at improving a woman's chances for survival and that both involve axillary node dissection. The second, which follows the Decision Board discussion, asks the patient to consider how each treatment option will affect her attitude, lifestyle, and personal appearance. A third card explains breast reconstruction.

All patient education cards and a smaller reproduction of the Decision Board are given to patients to take home with them so they can reflect further on their choices and discuss them with their family members and other physicians.

Using the board

The Decision Board was tested by two surgeons in university settings and five surgeons in community practice within the province of Ontario between June 1996 and November 1997. A total of 175 patients with Stage I or II adenocarcinoma were counseled using the Decision Board, and patients and surgeons were interviewed to assess the

effectiveness and acceptability of the tool.

According to the findings from this study, which were published in the June 1999 issue of the *Journal of Clinical Oncology*, the Decision Board was readily accepted by both patients. Ninety-eight percent of patients felt the Decision Board was easy to understand, and an equal percentage recommended that the decision aid should be used with other patients. Ninety-five percent of patients were satisfied with the information they obtained through the Decision Board, and 95 percent were satisfied with the decision-making process using the board. Eighty-one percent of patients believed the counseling instrument helped them make a treatment decision, and 62 percent said it helped them think of questions to ask.

The decision aid also scored highly in its ability to convey information to patients. Women achieved an average score of 84 percent on a true-false test of comprehension and a greater than 70 percent rate of correct responses for each question in the test.

Surgeons were comfortable using the counseling aid, which took an average of 21 minutes to administer. Surgeons reported that the tool was helpful in presenting information to patients in 91 percent of their consultations, and they were satisfied with the way the tool fostered decision making in 97 percent of the consultations. Even more revealing, said Whelan, were the surgeons' subjective opinions about the instrument. "When we spoke to the surgeons afterward, they said the tool was simple; it didn't cause them to change their practice dramatically. It also allowed them to give each woman a clear picture of her treatment options and make sure each woman was informed to the same degree," he said.

When Mirsky tested the Decision Board with 40 of his own patients, he found it reduced the amount of time he needed to deliver the same information he would give in a traditional consultation. The board helped frame the discussion because it organized information and addressed the same issues for each treatment option in a sequential fashion and the comparisons were clear and concise. "You have to embellish some of the items on the Decision Board, particularly when you talk about lymph node removal under the arm," Mirsky acknowledged, because he feels the decision aid does not include enough detail about the rationale be-

hind lymph node dissection or the complications that may arise from that portion of treatment.

As he pointed out, however, "Other decision aids are merely giving patients information. With this tool, your patients are looking at specific items of information, hearing you talk about these points, and asking questions at the same time, and you can pause and elaborate whenever you need to." The entire discussion is geared for enhancing communication between physician and patient. "The process is interactive. The patient is right there with me, so while I'm focusing on the lymph node portion of the panel, I'm grabbing a pen and drawing the axillary area myself, explaining why we need to remove the lymph nodes," Mirsky said.

At present, the paper version of the Decision Board is being studied in a randomized trial involving more than 30 surgeons in the province of Ontario, and a computer-based alternative is under development. Although the Decision Board is not currently available for purchase, Dr. Whelan will gladly discuss this educational tool with interested surgeons. More information may be obtained from Dr. Whelan, Hamilton Regional Cancer Center, 699 Concession St., Hamilton, ON L8V 5C2, Canada, 905/387-9711, ext. 4501. □

References

1. Siminoff LA, Fetting JH, Aeloff MD: Doctor-patient communication about breast cancer adjuvant therapy. *J Clin Oncology* 7:1192-1200, 1989.
2. MacKillop WJ, Stewart WE, Ginsburg AD, et al: Cancer patients' perceptions of their disease and its treatment. *Br J Cancer*, 58:355-358, 1988.
3. Margolese RG: Breast cancer surgery: Who chooses and how? *Can Med Assoc J*, 150:331-333, 1994.
4. Rose G: Reflections on the changing times. *BMJ*, 301:683-687, 1990.
5. Brock DW, Wartman SA: When competent patients make irrational choices. *New Engl J Med*, 332:1595-1599, 1990.

Appendix 3: Sample of Community Surgeon Letters

October 7, 1999

Dr. Whelan
Hamilton Regional Cancer Center
699 Concession St.
Hamilton, Ontario L8V5C5 Canada

Dear Dr. Whelan,

I found the recent article by Karen Sandrick regarding your breast cancer teaching tool to be very interesting and I believe it would compliment my own presentation very nicely. When the decision board is available, please send me an application so that I might incorporate it into my practice. It appears to be very well designed and parallels my teaching methods precisely. You have my best regards.

Sincerely,



October 4, 1999

Timothy Whelan, BChMSc
Hamilton Regional Cancer Center
699 Concession Street
Hamilton, Ontario L8V 5C2 Canada

Dear Dr. Whelan:

I read the article about the Decision Board you are studying to help patients select treatment for breast cancer. Since my whole patient population is that of people with breast disease, I would be very interested in any further information you have about this board. I would even be willing to participate in a study in using this.

Please send any further information to me at the above address. Thank you in advance for any help you can give me.

Very truly yours,

1

September 30, 1999

Dr. Timothy Whelan
Hamilton Regional Cancer Center
699 Concession Street
Hamilton, ON L8V5C2
CANADA

Dear Dr. Whelan:

Ours is a general surgical practice. We see cancer patients on a weekly basis. Today, one of our surgeons ran across an article in the September 1999 issue of the American College of Surgeons Bulletin regarding your development of the Decision Board for mastectomy and lumpectomy. We understand that currently the Board is not available for purchase. However, we would appreciate any information you can share regarding this educational tool.

Thank you in advance for your assistance. We look forward to hearing from you.

Sincerely,

[Handwritten signature]

September 28, 1999

Dr. Timothy Whelan
Hamilton Regional Cancer Center
699 Concession Street
Hamilton, ON L8V5C2 Canada

Dear Dr. Whelan:

I read the article in the Bulletin of the American College of Surgeons by Karen Sandrick regarding the Decision Board which you have developed. I would be very interested in knowing more about this and how this can be purchased when it is available. I do a considerable volume of breast surgery in my practice and think this would be most helpful in the education of my patients. After the Decision Board is available, if you are interested in any follow-up on how it is received by patients, I would be happy to participate in that.

Sincerely,

Appendix 4: Copies of Node-negative Instruments: 3 Risk Categories

QUESTIONS

1. Question:

Answer:

2. Question:

Answer:

3. Question:

Answer:

4. Question:

Answer:

5. Question:

Answer:

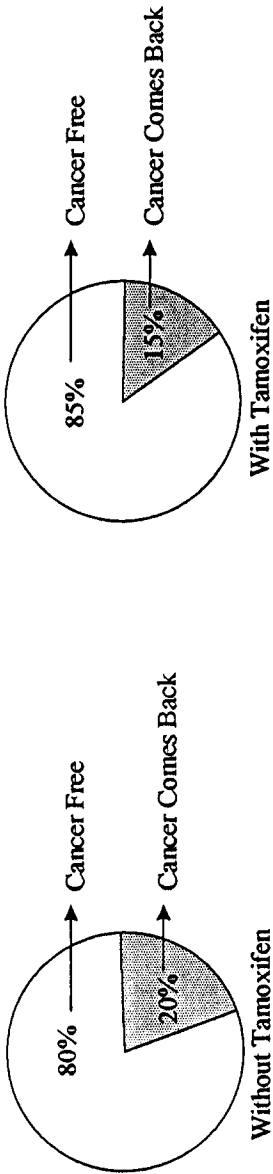
DECISION BOARD

INTRODUCTION

Recently, you had surgery for cancer of the breast. The surgeon has removed the cancerous lump and some of the lymph nodes (glands) under your arm. No cancer has spread to these nodes.

Even though the cancer was removed we know, from other patients like yourself, that there is a chance the cancer will come back. It may come back in the same breast where the surgery was performed (local recurrence) or it may come back in other parts of the body, such as the bone, lung, or liver (distant recurrence). Cancer that comes back in the breast can be treated with further surgery. Breast cancer that comes back in other parts of the body can be treated, but usually cannot be cured.

It is important for you to know that Tamoxifen will reduce your chances of cancer coming back. Approximately 20 out of 100 women with breast cancer like yourself will experience the cancer coming back in the next seven years without Tamoxifen. With Tamoxifen, 15 out of 100 women will experience the cancer coming back.



Recent scientific studies have also shown that chemotherapy in addition to Tamoxifen may further prevent the cancer from returning. We would like to discuss the benefits and side effects of chemotherapy.

It must be emphasized that, as far as we can tell, there is no evidence that the cancer has spread. We are talking about chemotherapy as an additional treatment to help prevent the cancer from coming back, but it may not work in all cases.

Chemotherapy drugs given by mouth (orally) and by injection (intravenously) can cause side effects. These side effects are only temporary. Balanced against them is the hope that the cancer can be prevented from coming back. We would like to discuss chemotherapy and its potential benefits and side effects with you further.

NO CHEMOTHERAPY (Tamoxifen only)

You have chosen not to have chemotherapy. You will continue to take Tamoxifen, 1 tablet a day, for 5 years. You will be followed at the cancer clinic at regular intervals. At these visits, your doctor will ask how you are feeling. Then you will have a physical examination and some blood tests. On occasion, you may have other tests if the doctor feels they are necessary. Once a year your doctor will ask you to have a mammogram.

CHEMOTHERAPY (in addition to Tamoxifen)

You have chosen to have chemotherapy. Chemotherapy is a treatment program of cancer fighting drugs. The drugs are given by injection (intravenously) as well as by mouth (orally). You must visit the clinic once a week for two weeks each month to receive the injected drugs. The visit takes about two hours including waiting time. At this appointment, a blood sample is taken. Then you are seen by the doctor or nurse. Afterwards, you go to the chemotherapy room and sit in a comfortable chair. Two drugs are given through a small needle inserted into the back of your hand. This takes 10-15 minutes.

You must take several pills at home. These pills are taken every day for the same two-week period as your clinic visits. After the first two weeks, you get two weeks off. Then the cycle repeats. You receive a total of 6 months treatment.

There are a number of possible side effects of treatment. The following are examples of some of the most common side effects:

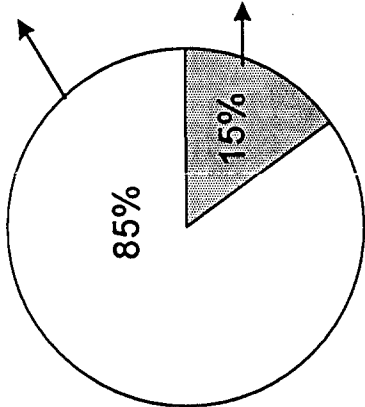
- o About half of the women lose their hair. The hair loss is not permanent. It always grows back once the treatment stops. Most women choose to wear a wig until their hair grows back.
- o Some women have stomach upset or vomiting. This can often be prevented or controlled with mild medicine. A small number of women (about 1 out of 10 persons) require stronger medicine to control their nausea.
- o Some women describe feeling tired a good deal of the time. This may (or may not) interfere with their usual work or social activity.
- o Some women report burning watery eyes.
- o Some women report increased production of gas or constipation.
- o Some women report being teary or unhappy.
- o Rarely women develop infection requiring hospitalization and antibiotic treatment.

Following chemotherapy:

- o Many women report a gain in weight of 5-10 pounds in the first year.
- o Some women develop early menopause with permanent loss of periods.

Measures are available to help you cope with these side effects.

After you have completed chemotherapy, you will begin taking Tamoxifen, 1 tablet a day for 5 years. You will continue to be followed at the cancer clinic on a regular basis. At these visits, a blood sample is taken. Then you are interviewed by your doctor and given a physical examination. On occasion, you may have other tests if the doctor feels they are necessary. Once a year your doctor will ask you to have a mammogram.



All tests and examinations in the coming seven years show that you are free of cancer. You will continue to be followed at the cancer clinic beyond seven years. Even though all tests show you are cancer-free, from time to time you may worry about the cancer coming back.

CANCER COMES BACK (RECURRENCE)

Within the next seven years, the breast cancer may come back. It can come back in the same breast where the surgery was performed (local recurrence), or it may come back in other parts of the body, such as the bone, lung or liver (distant recurrence).

If the cancer returns in the breast, it is often seen as a small lump in your breast. The lump is painless, but causes worry and upset. It is usually removed by a surgeon. Sometimes the surgeon will remove the whole breast (called mastectomy). Recurrence of cancer in the breast is rare and does not necessarily mean that the cancer will come back in other parts of the body.

Breast cancer that comes back in other parts of the body (or spreads):

- to the bone can be painful;
- to the liver can be painful and can cause swelling in the abdomen (belly);
- to the lungs can cause respiratory symptoms, such as coughing and shortness of breath;
- to the brain can cause headaches, weakness, confusion and difficulty walking.

Many women whose cancer comes back in other parts of the body receive further treatment which may be chemotherapy, hormonal therapies, radiation therapy, and/or pain medicine. In many women this treatment helps to shrink tumours and relieve symptoms. Sometimes a patient will have to come into the hospital to receive care.

Unfortunately, a patient whose cancer comes back in other parts of the body will eventually die from the disease.

CANCER-FREE (NO RECURRENCE)

All tests and examinations in the coming seven years show that you are free of cancer. You will continue to be followed at the cancer clinic beyond seven years. Even though all tests show you are cancer-free, from time to time you may worry about the cancer coming back.

CANCER COMES BACK (RECURRENCE)

Within the next seven years, the breast cancer may come back. It can come back in the same breast where the surgery was performed (local recurrence), or it may come back in other parts of the body, such as the bone, lung or liver (distant recurrence).

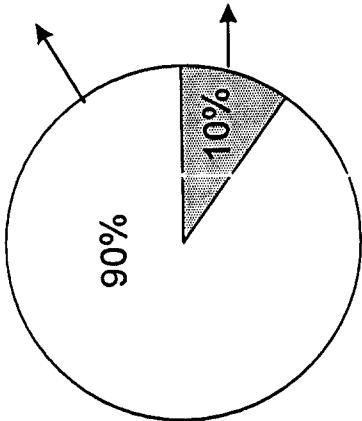
If the cancer returns in the breast, it is often seen as a small lump in your breast. The lump is painless, but causes worry and upset. It is usually removed by a surgeon. Sometimes the surgeon will remove the whole breast (called mastectomy). Recurrence of cancer in the breast is rare and does not necessarily mean that the cancer will come back in other parts of the body.

Breast cancer that comes back in other parts of the body (or spreads):

- to the bone can be painful;
- to the liver can be painful and can cause swelling in the abdomen (belly);
- to the lungs can cause respiratory symptoms, such as coughing and shortness of breath;
- to the brain can cause headaches, weakness, confusion and difficulty walking.

Many women whose cancer comes back in other parts of the body receive further treatment which may be chemotherapy, hormonal therapies, radiation therapy, and/or pain medicine. In many women this treatment helps to shrink tumours and relieve symptoms. Sometimes a patient will have to come into the hospital to receive care.

Unfortunately, a patient whose cancer comes back in other parts of the body will eventually die from the disease.



QUESTIONS

1. Question:	
Answer:	
2. Question:	
Answer:	
3. Question:	
Answer:	
4. Question:	
Answer:	
5. Question:	
Answer:	

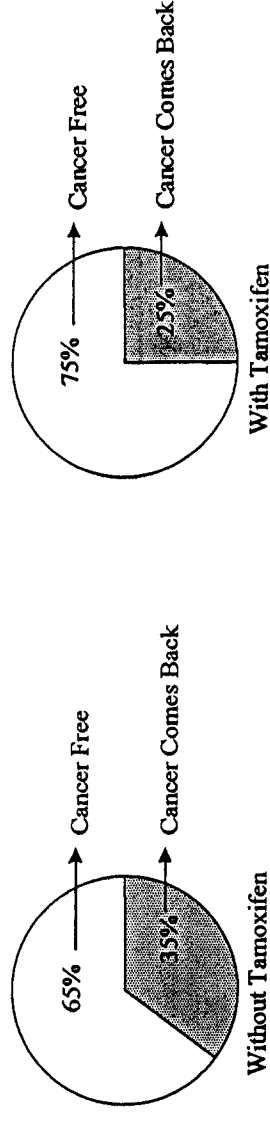
DECISION BOARD

INTRODUCTION

Recently, you had surgery for cancer of the breast. The surgeon has removed the cancer and some of the lymph nodes (glands) under your arm. No cancer has spread to these nodes.

Even though the cancer was removed we know, from other patients like yourself, that there is a chance the cancer will come back. It may come back in the area of the breast surgery (local recurrence) or it may come back in other parts of the body, such as the bone, lung, or liver (distant recurrence). Cancer that comes back in the breast area can be treated with further surgery. Breast cancer that comes back in other parts of the body can be treated, but usually cannot be cured.

It is important for you to know that Tamoxifen will reduce your chances of cancer coming back. Approximately 35 out of 100 women with breast cancer like yourself will experience the cancer coming back in the next seven years without Tamoxifen. With Tamoxifen, 25 out of 100 women will experience the cancer coming back.



Recent scientific studies have shown that chemotherapy in addition to Tamoxifen may further prevent the cancer from returning. We would like to discuss the benefits and side effects of chemotherapy.

It must be emphasized that, as far as we can tell, there is no evidence that the cancer has spread. We are talking about chemotherapy as an additional treatment to help prevent the cancer from coming back, but it may not work in all cases.

Chemotherapy drugs given by mouth (orally) and by injection (intravenously) can cause side effects. These side effects are only temporary. Balanced against them is the hope that the cancer can be prevented from coming back. We would like to discuss chemotherapy and its potential benefits and side effects with you further.

DECISION BOARD

TREATMENT CHOICE

NO CHEMOTHERAPY (Tamoxifen only)

You have chosen not to have chemotherapy. You will continue to take Tamoxifen, 1 tablet a day, for 5 years. You will be followed at the cancer clinic at regular intervals. At these visits, your doctor will ask how you are feeling. Then you will have a physical examination and some blood tests. On occasion, you may have other tests if the doctor feels they are necessary. Once a year your doctor will ask you to have a mammogram.

CHEMOTHERAPY (in addition to Tamoxifen)

You have chosen to have chemotherapy. Chemotherapy is a treatment program of cancer fighting drugs. The drugs are given by injection (intravenously) as well as by mouth (orally). You must visit the clinic once a week for two weeks each month to receive the injected drugs. The visit takes about two hours including waiting time. At this appointment, a blood sample is taken. Then you are seen by the doctor or nurse. Afterwards, you go to the chemotherapy room and sit in a comfortable chair. Two drugs are given through a small needle inserted into the back of your hand. This takes 10-15 minutes.

You must take several pills at home. These pills are taken every day for the same two-week period as your clinic visits. After the first two weeks, you get two weeks off. Then the cycle repeats. You receive a total of 6 months treatment.

There are a number of possible side effects of treatment. The following are examples of some of the most common side effects:

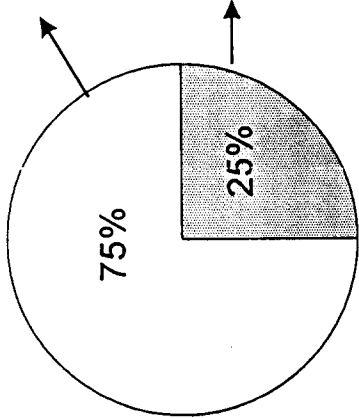
- o About half of the women lose their hair. The hair loss is not permanent. It always grows back once the treatment stops. Most women choose to wear a wig until their hair grows back.
- o Some women have stomach upset or vomiting. This can often be prevented or controlled with mild medicine. A small number of women (about 1 out of 10 persons) require stronger medicine to control their nausea.
- o Some women describe feeling tired a good deal of the time. This may (or may not) interfere with their usual work or social activity.
- o Some women report burning watery eyes.
- o Some women report increased production of gas or constipation.
- o Some women report being teary or unhappy.
- o Rarely women develop infection requiring hospitalization and antibiotic treatment.

Following chemotherapy:

- o Many women report a gain in weight of 5-10 pounds in the first year.
 - o Some women develop early menopause with permanent loss of periods.
- Measures are available to help you cope with these side effects.

After you have *completed* chemotherapy, you will begin taking *Tamoxifen*, 1 tablet a day for 5 years. You will continue to be followed at the cancer clinic on a regular basis. At these visits, a blood sample is taken. Then you are interviewed by your doctor and given a physical examination. On occasion, you may have other tests if the doctor feels they are necessary. Once a year your doctor will ask you to have a mammogram.

49 CHANCE OF OUTCOME



You have chosen not to have chemotherapy. You will continue to take Tamoxifen, 1 tablet a day, for 5 years. You will be followed at the cancer clinic at regular intervals. At these visits, your doctor will ask how you are feeling. Then you will have a physical examination and some blood tests. On occasion, you may have other tests if the doctor feels they are necessary. Once a year your doctor will ask you to have a mammogram.

CHEMOTHERAPY (in addition to Tamoxifen)

You have chosen to have chemotherapy. Chemotherapy is a treatment program of cancer fighting drugs. The drugs are given by injection (intravenously) as well as by mouth (orally). You must visit the clinic once a week for two weeks each month to receive the injected drugs. The visit takes about two hours including waiting time. At this appointment, a blood sample is taken. Then you are seen by the doctor or nurse. Afterwards, you go to the chemotherapy room and sit in a comfortable chair. Two drugs are given through a small needle inserted into the back of your hand. This takes 10-15 minutes.

You must take several pills at home. These pills are taken every day for the same two-week period as your clinic visits. After the first two weeks, you get two weeks off. Then the cycle repeats. You receive a total of 6 months treatment.

There are a number of possible side effects of treatment. The following are examples of some of the most common side effects:

- o About half of the women lose their hair. The hair loss is not permanent. It always grows back once the treatment stops. Most women choose to wear a wig until their hair grows back.
- o Some women have stomach upset or vomiting. This can often be prevented or controlled with mild medicine. A small number of women (about 1 out of 10 persons) require stronger medicine to control their nausea.
- o Some women describe feeling tired a good deal of the time. This may (or may not) interfere with their usual work or social activity.
- o Some women report burning watery eyes.
- o Some women report increased production of gas or constipation.
- o Some women report being teary or unhappy.
- o Rarely women develop infection requiring hospitalization and antibiotic treatment.

Following chemotherapy:

- o Many women report a gain in weight of 5-10 pounds in the first year.
 - o Some women develop early menopause with permanent loss of periods.
- Measures are available to help you cope with these side effects.

After you have *completed* chemotherapy, you will begin taking *Tamoxifen*, 1 tablet a day for 5 years. You will continue to be followed at the cancer clinic on a regular basis. At these visits, a blood sample is taken. Then you are interviewed by your doctor and given a physical examination. On occasion, you may have other tests if the doctor feels they are necessary. Once a year your doctor will ask you to have a mammogram.

49 CHANCE OF OUTCOME

OUTCOME

CANCER-FREE (NO RECURRENCE)

All tests and examinations in the coming seven years show that you are free of cancer. You will continue to be followed at the cancer clinic beyond seven years. Even though all tests show you are cancer-free, from time to time you may worry about the cancer coming back.

CANCER COMES BACK (RECURRENCE)

Within the next seven years, the breast cancer may come back. It can come back in the area of the breast surgery (local recurrence), or it may come back in other parts of the body, such as the bone, lung or liver (distant recurrence).

If the cancer returns, it is often seen as a small lump on the chest wall. The lump is painless, but causes worry and upset. It is usually removed by a surgeon followed by radiation to the area. In many patients recurrence on the chest wall is followed at some time later by spread to other parts of the body.

Breast cancer that comes back in other parts of the body (or spreads):

- to the bone can be painful;
- to the liver can be painful and can cause swelling in the abdomen (belly);
- to the lungs can cause respiratory symptoms, such as coughing and shortness of breath;
- to the brain can cause headaches, weakness, confusion and difficulty walking.

Many women whose cancer comes back in other parts of the body receive further treatment which may be chemotherapy, hormonal therapies, radiation therapy, and/or pain medicine. In many women this treatment helps to shrink tumours and relieve symptoms. Sometimes a patient will have to come into the hospital to receive care.

Unfortunately, a patient whose cancer comes back in other parts of the body will eventually die from the disease.

CANCER-FREE (NO RECURRENCE)

All tests and examinations in the coming seven years show that you are free of cancer. You will continue to be followed at the cancer clinic beyond seven years. Even though all tests show you are cancer-free, from time to time you may worry about the cancer coming back.

CANCER COMES BACK (RECURRENCE)

Within the next seven years, the breast cancer may come back. It can come back in the area of the breast surgery (local recurrence), or it may come back in other parts of the body, such as the bone, lung or liver (distant recurrence).

If the cancer returns, it is often seen as a small lump on the chest wall. The lump is painless, but causes worry and upset. It is usually removed by a surgeon followed by radiation to the area. In many patients recurrence on the chest wall is followed at some time later by spread to other parts of the body

Breast cancer that comes back in other parts of the body (or spreads):

- to the bone can be painful;
- to the liver can be painful and can cause swelling in the abdomen (belly);
- to the lungs can cause respiratory symptoms, such as coughing and shortness of breath;
- to the brain can cause headaches, weakness, confusion and difficulty walking.

Many women whose cancer comes back in other parts of the body receive further treatment which may be chemotherapy, hormonal therapies, radiation therapy, and/or pain medicine. In many women this treatment helps to shrink tumours and relieve symptoms. Sometimes a patient will have to come into the hospital to receive care.

Unfortunately, a patient whose cancer comes back in other parts of the body will eventually die from the disease.

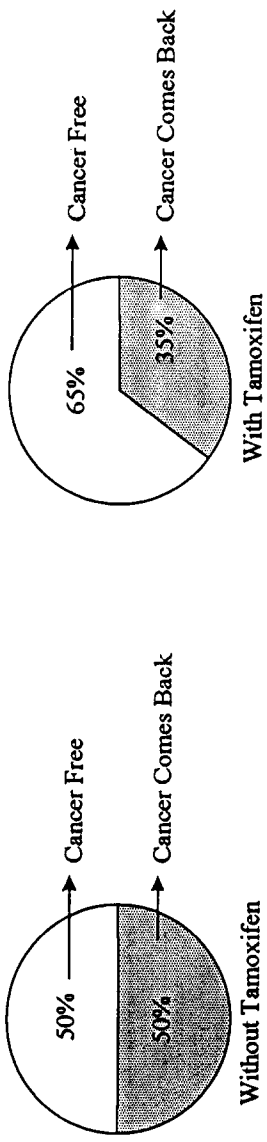
DECISION BOARD

INTRODUCTION

Recently, you had surgery for cancer of the breast. The surgeon has removed the cancerous lump and some of the lymph nodes (glands) under your arm. No cancer has spread to these nodes.

Even though the cancer was removed we know, from other patients like yourself, that there is a chance the cancer will come back. It may come back in the same breast where the surgery was performed (local recurrence) or it may come back in other parts of the body, such as the bone, lung, or liver (distant recurrence). Cancer that comes back in the breast can be treated with further surgery. Breast cancer that comes back in other parts of the body can be treated, but usually cannot be cured.

It is important for you to know that Tamoxifen will reduce your chances of cancer coming back. Approximately 50 out of 100 women with breast cancer like yourself will experience the cancer coming back in the next seven years without Tamoxifen. With Tamoxifen, 35 out of 100 women will experience the cancer coming back.



Recent scientific studies have also shown that chemotherapy in addition to Tamoxifen may further prevent the cancer from returning. We would like to discuss the benefits and side effects of chemotherapy.

It must be emphasized that, as far as we can tell, there is no evidence that the cancer has spread. We are talking about chemotherapy as an additional treatment to help prevent the cancer from coming back, but it may not work in all cases.

Chemotherapy drugs given by mouth (orally) and by injection (intravenously) can cause side effects. These side effects are only temporary. Balanced against them is the hope that the cancer can be prevented from coming back. We would like to discuss chemotherapy and its potential benefits and side effects with you further.

QUESTIONS

1. Question:

Answer:

2. Question:

Answer:

3. Question:

Answer:

4. Question:

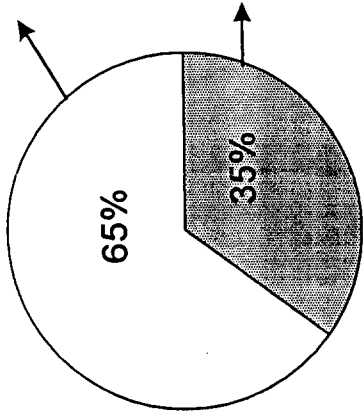
Answer:

5. Question:

Answer:

NO CHEMOTHERAPY (Tamoxifen only)

You have chosen not to have chemotherapy. You will continue to take Tamoxifen, 1 tablet a day, for 5 years. You will be followed at the cancer clinic at regular intervals. At these visits, your doctor will ask how you are feeling. Then you will have a physical examination and some blood tests. On occasion, you may have other tests if the doctor feels they are necessary. Once a year your doctor will ask you to have a mammogram.



CHEMOTHERAPY (in addition to Tamoxifen)

You have chosen to have chemotherapy. Chemotherapy is a treatment program of cancer fighting drugs. The drugs are given by injection (intravenously) as well as by mouth (orally). You must visit the clinic once a week for two weeks each month to receive the injected drugs. The visit takes about two hours including waiting time. At this appointment, a blood sample is taken. Then you are seen by the doctor or nurse. Afterwards, you go to the chemotherapy room and sit in a comfortable chair. Two drugs are given through a small needle inserted into the back of your hand. This takes 10-15 minutes.

You must take several pills at home. These pills are taken every day for the same two-week period as your clinic visits. After the first two weeks, you get two weeks off. Then the cycle repeats. You receive a total of 6 months treatment.

There are a number of possible side effects of treatment. The following are examples of some of the most common side effects:

- o About half of the women lose their hair. The hair loss is not permanent. It always grows back once the treatment stops. Most women choose to wear a wig until their hair grows back.
- o Some women have stomach upset or vomiting. This can often be prevented or controlled with mild medicine. A small number of women (about 1 out of 10 persons) require stronger medicine to control their nausea.
- o Some women describe feeling tired a good deal of the time. This may (or may not) interfere with their usual work or social activity.
- o Some women report burning watery eyes.
- o Some women report increased production of gas or constipation.
- o Some women report being teary or unhappy.
- o Rarely women develop infection requiring hospitalization and antibiotic treatment.

Following chemotherapy:

- o Many women report a gain in weight of 5-10 pounds in the first year.
- o Some women develop early menopause with permanent loss of periods.

Measures are available to help you cope with these side effects.

After you have completed chemotherapy, you will begin taking *Tamoxifen*, 1 tablet a day for 5 years. You will continue to be followed at the cancer clinic on a regular basis. At these visits, a blood sample is taken. Then you are interviewed by your doctor and given a physical examination. On occasion, you may have other tests if the doctor feels they are necessary. Once a year your doctor will ask you to have a mammogram.

CANCER-FREE (NO RECURRENCE)

All tests and examinations in the coming seven years show that you are free of cancer. You will continue to be followed at the cancer clinic beyond seven years. Even though all tests show you are cancer-free, from time to time you may worry about the cancer coming back.

CANCER COMES BACK (RECURRENCE)

Within the next seven years, the breast cancer may come back. It can come back in the same breast where the surgery was performed (local recurrence), or it may come back in other parts of the body, such as the bone, lung or liver (distant recurrence).

If the cancer returns in the breast, it is often seen as a small lump in your breast. The lump is painless, but causes worry and upset. It is usually removed by a surgeon. Sometimes the surgeon will remove the whole breast (called mastectomy). Recurrence of cancer in the breast is rare and does not necessarily mean that the cancer will come back in other parts of the body.

Breast cancer that comes back in other parts of the body (or spreads):

- to the bone can be painful;
- to the liver can be painful and can cause swelling in the abdomen (belly);
- to the lungs can cause respiratory symptoms, such as coughing and shortness of breath;
- to the brain can cause headaches, weakness, confusion and difficulty walking.

Many women whose cancer comes back in other parts of the body receive further treatment which may be chemotherapy, hormonal therapies, radiation therapy, and/or pain medicine. In many women this treatment helps to shrink tumours and relieve symptoms. Sometimes a patient will have to come into the hospital to receive care.

Unfortunately, a patient whose cancer comes back in other parts of the body will eventually die from the disease.

CANCER-FREE (NO RECURRENCE)

All tests and examinations in the coming seven years show that you are free of cancer. You will continue to be followed at the cancer clinic beyond seven years. Even though all tests show you are cancer-free, from time to time you may worry about the cancer coming back.

CANCER COMES BACK (RECURRENCE)

Within the next seven years, the breast cancer may come back. It can come back in the same breast where the surgery was performed (local recurrence), or it may come back in other parts of the body, such as the bone, lung or liver (distant recurrence).

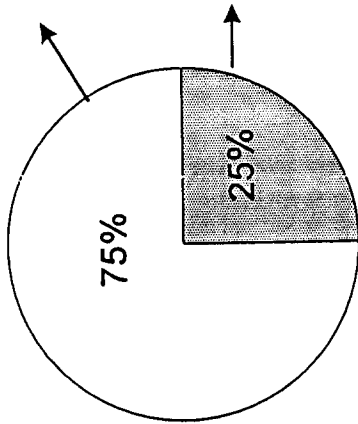
If the cancer returns in the breast, it is often seen as a small lump in your breast. The lump is painless, but causes worry and upset. It is usually removed by a surgeon. Sometimes the surgeon will remove the whole breast (called mastectomy). Recurrence of cancer in the breast is rare and does not necessarily mean that the cancer will come back in other parts of the body.

Breast cancer that comes back in other parts of the body (or spreads):

- to the bone can be painful;
- to the liver can be painful and can cause swelling in the abdomen (belly);
- to the lungs can cause respiratory symptoms, such as coughing and shortness of breath;
- to the brain can cause headaches, weakness, confusion and difficulty walking.

Many women whose cancer comes back in other parts of the body receive further treatment which may be chemotherapy, hormonal therapies, radiation therapy, and/or pain medicine. In many women this treatment helps to shrink tumours and relieve symptoms. Sometimes a patient will have to come into the hospital to receive care.

Unfortunately, a patient whose cancer comes back in other parts of the body will eventually die from the disease.



QUESTIONS

55

1. Question: _____

Answer: _____

2. Question: _____

Answer: _____

3. Question: _____

Answer: _____

4. Question: _____

Answer: _____

5. Question: _____

Answer: _____

Appendix 5: Irwin E, Arnold A, Whelan TJ, Reyno LM, Cranton P. Offering a choice between two adjuvant chemotherapy regimens: A pilot study to develop a decision aid for women with breast cancer. Patient Education and Counselling 1999; 37:283-291.



ELSEVIER

Patient Education and Counseling 37 (1999) 283–291

PATIENT EDUCATION
AND COUNSELING

Offering a choice between two adjuvant chemotherapy regimens: a pilot study to develop a decision aid for women with breast cancer[☆]

Ellen Irwin^{a,c,*}, Andrew Arnold^{b,c}, Timothy J. Whelan^{b,c}, Leonard M. Reyno^{b,c},
Patricia Cranton^d

^aMcMaster University, School of Nursing, 1200 Main Street West, Hamilton, Ontario L8N 3Z5, Canada

^bDepartment of Medicine, 1200 Main Street West, Hamilton, Ontario L8N 3Z5, Canada

^cOCTRF Hamilton Regional Cancer Centre, 699 Concession St., Hamilton, Ontario L8V 5C2, Canada

^dBrock University, Faculty of Education, 500 Glenridge Ave., St. Catharines, Ontario L2S 3A1, Canada

Received 20 January 1998; received in revised form 7 July 1998; accepted 18 August 1998

Abstract

Background: The primary objective of this study was to develop a decision aid which would encourage and assist patients to become involved in treatment decision making, and help clinicians to objectively educate patients about the benefits and risks of adjuvant chemotherapy for breast cancer. A secondary objective was to investigate the factors influencing this treatment decision-making process for women when choosing between adriamycin and cyclophosphamide (AC) versus cyclophosphamide, methotrexate and 5-fluorouracil (CMF) chemotherapy. **Methods:** An educational visual instrument called a Decision Board was developed consisting of written and graphical material. The Decision Board displays general information about chemotherapy and detailed information about each chemotherapy regimen, including the schedule and side effects, and was presented to patients with a scripted standardized oral explanation. The instrument was evaluated in 46 premenopausal women newly diagnosed with node-positive breast cancer. Following presentation of the board, the patients were given a take-home version to review and asked to return 1–2 weeks later with a decision. During the second visit each patient was asked to complete a questionnaire regarding demographics, learning and comprehension, treatment preference, and factors influencing their decision. **Results:** Recall of information was acceptable ($\geq 80\%$). The Decision Board was found helpful by all, but the level of difficulty with decision making was variable. Out of 46 women, 23 women chose AC, 21 chose CMF, and two chose no treatment. The major factors affecting treatment preference were related to the impact on quality of life, the length of therapy, and the side effects, in particular, vomiting and alopecia. **Conclusions:** The Decision Board appears to be a valuable educational tool that enables patients to become well-informed and directly involved in their treatment decisions. © 1999 Elsevier Science Ireland Ltd. All rights reserved.

Keywords: Breast neoplasm; Adjuvant chemotherapy; Patient education; Treatment decision making; Quality of life

*Corresponding author. Tel.: +1-905-3879495/9711 ext. 5920; fax: +1-905-5756317.

[☆]This work was presented in part at the 17th Annual San Antonio Breast Cancer Symposium in San Antonio, Texas, USA, December 8–10, 1994 and the Annual Meeting of The American Society of Clinical Oncology in Los Angeles, California, USA, May 20–23, 1995.

1. Introduction

The role of patients in medical decision making has become increasingly important and has led to a greater emphasis on patient education and informed decision making in the provision of health care.

Oncology health care professionals and their patients are often confronted with treatment decisions that may not only impact survival but may have a significant impact on the patient's quality of life. In these instances both the associated benefits and risks must be considered and a choice made. The concept of shared decision making, also referred to as shared control, between the patient and health care team is emerging as an important concept in oncology practice. The provision of information along with the opportunity to participate in the management of his or her own health care acknowledges individuality and personal preference. However, the optimal method of facilitating patient decision making is not known.

Research has shown that more and more patients prefer to be informed and involved, at least to some extent, in decisions regarding their own care. Increased patient participation in treatment decision making may improve hope for a favourable outcome [1] and patient compliance [2]. Several studies have indicated that some oncology patients, prefer to share treatment control with their physicians and be involved in the treatment decision making process [1,3,4]. The patients who prefer a more active role are often female [4,5], younger [1,4-6], well-educated [1,5,6], and have a reproductive cancer such as breast cancer [5]. Those offered participation in treatment decisions show better psychological adjustment [7-9] and greater satisfaction with their medical care [6,10] than those not given a choice.

There is little controversy concerning the recommendation of adjuvant chemotherapy for premenopausal women with axillary node-positive breast cancer. A recent meta-analysis demonstrated, for women younger than 50 years of age, a reduction in recurrence with an odds ratio of $0.64 \pm .05$, $P < .00001$, and a reduction in death with an odds ratio of $.75 \pm .06$, $P < .0001$, with poly-chemotherapy [11]. In addition, recent data suggest that some regimens are equally efficacious. The NSABP clinical trial, B-15, has demonstrated that four 21-day cycles of doxorubicin (adriamycin) and cyclophosphamide (AC) and six 28-day cycles of cyclophosphamide, methotrexate, and 5-fluorouracil (CMF) are equally effective adjuvant chemotherapy regimens for treating premenopausal women with axillary node positive breast cancer in terms of disease-free survival and overall survival [12]. However, these regimens

differ with regards to toxicity, treatment schedule, route of administration, duration of treatment, and the number of required clinic visits, all of which may affect a person's perceived quality of life. Therefore, the choice between AC and CMF must be based upon factors which affect a person's quality of life. In view of the importance of patient involvement in such a decision we wanted to develop a method whereby information regarding the benefits and risks of AC and CMF could be presented to a woman and she could state a preference.

The use of visual educational decision aids, called Decision Boards, to assist in the transfer of information concerning treatment options is a relatively new concept. Previously these aids have been used with patients with axillary node-negative breast cancer to offer them a choice between adjuvant therapy or no further treatment [13,14]. Levine et al. [13] and Whelan et al. [14] presented women with the side effects of treatment versus the modest but significant improvement in outcome. Patients who used such an instrument chose one option over the other for various reasons. However, because the choice of active treatment offered improved survival [13] or increased freedom from local recurrence [14] the predominant reason for choosing treatment was probably the perceived additional benefit offered.

We describe here a study conducted with consecutive premenopausal patients who presented with axillary node-positive breast cancer. The primary objective was to develop an instrument to facilitate women to participate in a treatment decision regarding the type of adjuvant chemotherapy. We wanted to explore the feasibility of this approach within a busy outpatient oncology clinic and to explore the educational value of the Decision Board by measuring patient comprehension. A secondary objective was to examine the factors affecting the decision-making process for newly diagnosed patients when choosing between two equally effective adjuvant chemotherapy regimens. We anticipated that factors relating to a patient's personal perception of quality of life, such as short-term or long-term toxicity, and convenience would predominate.

2. Methods

Our aim was to develop an instrument that would

be acceptable to patients and clinicians, easy to understand and helpful in decision making.

2.1. Instrument development

A Decision Board was developed to assist women with node-positive breast cancer to choose between two adjuvant chemotherapy treatments, AC and CMF, using a framework previously described [13-15]. The content of the Decision Board was based upon information from the clinical trial [12] with input from the oncologists and nurses of the breast cancer clinic as well as women currently undergoing treatment for breast cancer. The details regarding treatment schedule and the incidence of side effects were obtained from the randomized study [12]. A written script was developed to accompany the Decision Board to maintain consistency during presentation.

The Decision Board (75 × 45 cm) was designed in

three sections. The first provided general information about chemotherapy, the second provided details of the treatment schedule, and the third section displayed the incidence of nausea, vomiting, and alopecia associated with each regimen [12], see Fig. 1. The clinician read aloud the written material and explained the graphical information contained on seven cards and placed them on the board in sequence. Some additional information was given about less common side effects associated with each treatment but not included on the Board. These details, contained in the script, were thought to be relevant and important for informed decision making. It should be noted that the incidence of nausea and vomiting reported in the results of the clinical trial [12] occurred prior to the general acceptance and use of 5-HT₃ antagonists as antiemetics. In this study, women were routinely informed, and reminded in the script, that ondansetron was now available and that it may help reduce the risk of vomiting [16,17].

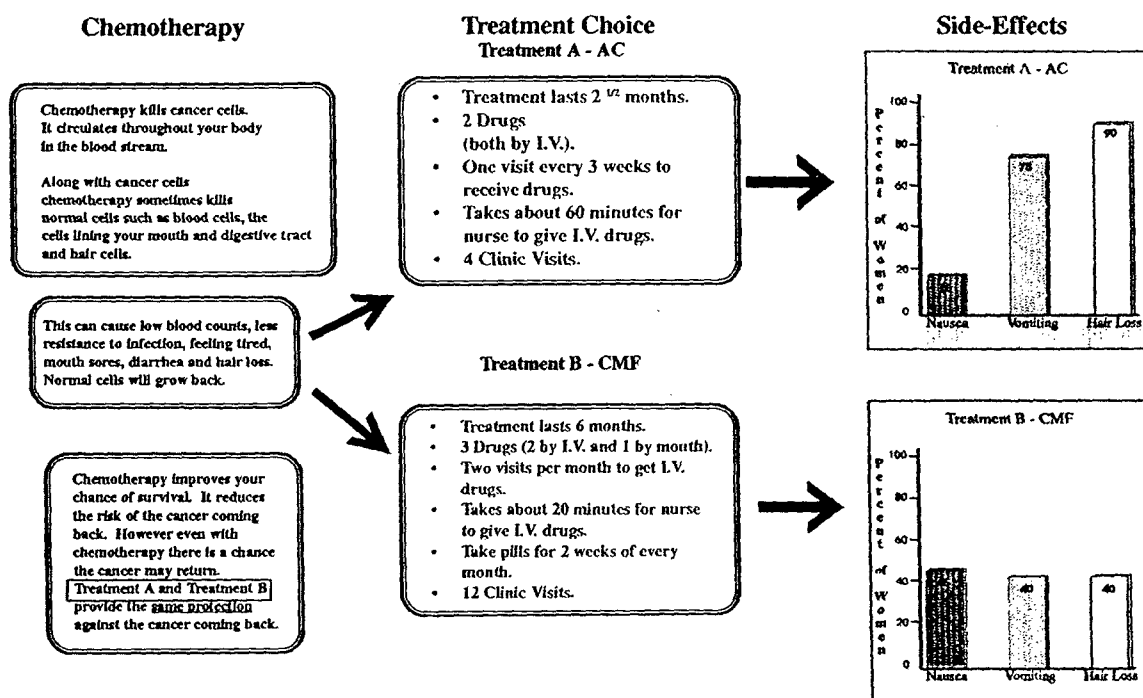


Fig. 1. Schematic depiction of the decision board. A more detailed description is available from the authors upon request.

A questionnaire was developed to assess demographic information, learning and comprehension, and the factors affecting the decision making process. Demographic information including age, marital status, number of children, child care, employment, income, education, and religion was collected, as well as place of residence and the type of breast surgery. To assess learning and comprehension from the Decision Board the women were asked to respond yes, unsure, or no to eight statements regarding the potential benefits and risks of AC and CMF. Data related to acceptability was obtained by asking each woman to rate the Decision Board in terms of helpfulness. Participants were also asked to state their treatment choice, the level of difficulty they experienced while making their decision, and whether anyone had influenced their decision-making process.

Information regarding the factors affecting decision making was collected in two ways. First, an open-ended question asked each woman to list the top three reasons for making her treatment choice. Second, the following list of 15 factors, which were predicted to play a role in this treatment decision, appeared in the questionnaire: overall side effects; nausea; vomiting; hair loss; the number of venipunctures for bloodwork and treatment; the number of trips to the cancer centre; caring for your family (your role as a wife, mother, daughter, or sister); maintaining your home (your responsibilities alone or as part of a family — e.g., housework, meals, gardening); the age of your children; what your family might think; what your friends might think; the experience of a friend; returning to work; financial concerns (loss of income, child care, travel expenses); and maintaining your normal routine. The women were asked to rate the level of importance of each factor to their treatment decision using a three-point Likert scale from one to three, where one equalled 'very important', two equalled 'important', and three equalled 'not important/not applicable'.

All sections of the questionnaire were developed for this study [18]. The Decision Board, script, and questionnaire were written at a grade eight readability level according to the SMOG test [19].

2.2. Pretesting

Pretesting was performed on four women newly

diagnosed with breast cancer and seven healthy female volunteers. All subjects were administered the Decision Board and questionnaire to check for clarity of the instruments and procedures used in the study. Of the four women with breast cancer, two chose CMF and two chose AC. Of the seven volunteers, four women chose CMF and three chose AC. When the volunteers underwent repeat testing 2 weeks later all seven women expressed the same preference, Kappa statistic = 1, $P < .005$. This pretest provided evidence towards establishing reliability as the volunteers' choices and responses remained consistent on the first and second presentation. Previous instruments [13,14] were validated on healthy volunteers and in this case no formal validation process was undertaken in view of the positive results.

2.3. Sample

The study sample was 46 premenopausal women newly diagnosed with primary node-positive breast cancer who were referred for a medical oncology consultation following surgery. All subjects were English speaking, literate, and had signed an informed consent form.

2.4. Procedure/administration of board

Women who agreed to participate in the study were presented the Decision Board by a nurse. In an effort to take into account order of presentation, each woman was randomized to receive one of two versions of the Decision Board. One version displayed CMF first (Version One) while the other displayed AC first (Version Two). This was to determine whether the order in which the treatment options were presented influenced choice.

The Decision Board was presented by the research nurse for the first 30 patients. One of four primary care nurses presented the board to the remaining patients in order to further test the instrument with the staff as part of the clinic routine. Each patient was informed that she need not make a decision during this clinic visit and was given a 28 × 43 cm photocopy of the Decision Board as well as a copy of the script to take home and consider. A return appointment was given for 1 or 2 weeks later at which time she was asked to have made a decision.

Upon the patient's return visit, she was asked to state her treatment preference and offered the opportunity to ask questions related to her choice. At this time each woman completed the full questionnaire.

2.5. Statistical analysis

All questionnaire responses were coded and entered into a database system. Statistical analyses were conducted using the SPSS software package. Descriptive statistics were generated for the demographic and outcome variables. A χ^2 test was used to compare the frequencies of responses for the non-parametric data and treatment choice by the Decision Board version for some of the demographic items and decision-making questions. The list of factors that were predicted to play a role in the treatment decision were analyzed in the following manner. Mean importance score for the reasons for a patient's choice was determined. For patients who chose AC versus those who chose CMF, a *t*-test was used to compare the mean scores for each factor. An analysis of variance was not performed due to the small sample size and number of variables.

3. Results

All eligible women were approached and all agreed to participate. Data collection took place in

the new patient breast cancer clinic at the Hamilton Regional Cancer Centre over 26 weeks for the first 30 patients and over a further 21 weeks for the final 16 patients.

3.1. Demographic data

Information regarding age, marital status, children, child care, employment, income, education, and the type of breast surgery is summarized in Table 1. The mean age of all participants was 45.5 years, ranging from 34 to 53 with a median of 48 years. Of the 46 women, 24 had had a mastectomy and 22 had had breast conserving surgery.

3.2. Learning and comprehension

The percent of correct responses for the eight questions ranged from 80 to 100% as shown in Table 2. No significant difference was found between the responses of the women in the two treatment choice groups.

3.3. Acceptability of the decision board

Clinician acceptability was high. Subjective feedback obtained from both the nurses and physicians in the clinic revealed that they found the Board useful, particularly since it presented the information in a uniform and objective manner.

Table 1
Demographics

Variable:	ALL (n = 46)			AC (n = 23)			CMF (n = 21)		
	Mean	Median	Range	Mean	Median	Range	Mean	Median	Range
Age:	45.5	48.0	34-53	45.3	49.0	34-52	46.2	47.0	35-53
		n	%		n	%		n	%
Marital status (married)		35	76		16	70		18	86
Children (of any age)		36	78		15	65		20	95
Child care available		24	52		11	48		13	62
Child care not appl.		19	41		10	43		8	38
Employed		29	63		13	57		14	67
Position prof/sr.mgmt/skilled		31	67		16	70		14	67
Family income \geq \$30,000		29	63		14	61		14	67
Education \geq high school		39	85		20	87		18	86
Mastectomy		24	52		16	70		7	33
Breast-conserving Surgery		22	48		7	30		14	67

Table 2
Learning and comprehension statements

	No. correct	%
Chemotherapy can kill cancer cells and normal cells in the body	44	96
Normal cells can recover from chemotherapy and grow again	42	91
AC and CMF offer the same chance of survival, they both help prevent the cancer from coming back	40	87
AC takes 4 months to finish	37	80
CMF means coming to the centre 12 times for treatment	42	91
AC means getting chemotherapy through an intravenous and by taking pills	37	80
There is a greater chance of vomiting with CMF	38	83
There is a greater chance of losing my hair with AC	42	91

The time required to administer the Decision Board ranged from 15 to 30 min depending upon the number of questions asked. The time required to complete the questionnaire ranged from 10 to 25 min.

The Decision Board was rated 'quite helpful' and 'very helpful' by 98% of the women and 'somewhat helpful' by the remainder. However, responses to the level of difficulty with decision making varied across a five-point scale from 'very much' to 'not at all'. Fourteen participants (32%) answered 'not at all' while the responses of the other participants were almost equally divided amongst the other four options, 'a little bit' (18%), 'somewhat' (18%), 'quite a bit' (16%), and 'very much' (16%).

Participants were also asked if their decision was influenced by anyone and who that person was. Twenty-one (46%) answered a 'family member or friend' while 13 women (28%) stated 'no one' had influenced them. When asked, no patient indicated that a cancer centre nurse or physician had influenced their choice.

3.4. Treatment choice

Twenty-three women (50%) chose AC and 21 (46%) chose CMF. Two women chose no chemo-

therapy treatment. The demographic characteristics of the women who chose AC were similar to those who chose CMF. Of the twenty-four women who had had a mastectomy, sixteen chose AC and seven chose CMF and of the twenty-two women who had had breast-conserving surgery seven chose AC and fourteen chose CMF, $P = 0.03$.

There were no significant differences found between the number of women who chose AC or CMF related to whether they had been presented Version One (CMF first) or Version Two (AC first) of the Decision Board. Of the twenty-three women who were presented Version One of the Decision Board, ten (44%) chose AC while twelve (52%) chose CMF and one chose no treatment. Of the twenty-three women presented Version Two, thirteen (57%) chose AC while nine (39%) chose CMF and one chose no treatment.

3.5. Factors influencing choice

The list of responses to the open-ended question were compiled and grouped together according to certain themes resulting in the formation of nine categories. The side effects category included specific reasons containing the words 'vomiting', 'hair loss', 'nausea', 'heart effects', and 'side effects' in general. The 'impact on quality of life' category included general statements relating to the effects of treatment on physical and psychological functioning as well as comments made about maintaining or returning to a state of normal or wellness. 'Time' referred to the overall treatment duration. 'Family concerns' took into account reasons relating to children, husband, or parents. 'Treatment schedule' included comments about the number of treatments, intravenous starts, and needle punctures, as well as, the time between treatments, the route of administration, and the monitoring by health care professionals throughout the chemotherapy regimen. 'Treatment efficacy' included statements in which the treatments were thought to be equally effective, one treatment was thought to be better than the other, and the treatment was known to be effective. 'Number of trips and distance' included reasons referring to transportation and the number of required trips or visits to the clinic. Work referred to employment

Table 3
Most important reasons by treatment choice

Reasons	ALL	AC	CMF
First	Side effects	Time	Side effects
Second	Impact on quality of life	Impact on quality of life	Impact on quality of life
Third	Time	Number of trips	Treatment schedule

reasons. 'The influence of others' referred to statements which quoted the opinions of others outside of family members such as a friend and a family physician.

The most common reason for choice given by the whole sample was side effects. This was followed by impact on quality of life and then time. Those who chose AC gave time as the most popular reason for their choice followed by impact on quality of life and then the number of trips. Those who chose CMF stated side effects as their most common reason for choice followed by impact on quality of life and then treatment schedule (Table 3). The particular side effects stated the most often were vomiting and alopecia.

Table 4
Comparison of factors across treatments

Variable	No. of cases	Mean	S.D.	P
Overall side effects				
AC	20	1.85	0.59	.000
CMF	17	1.12	0.33	
Nausea				
AC	21	2.05	0.67	.004
CMF	19	1.42	0.61	
Vomiting				
AC	21	2.05	0.67	.000
CMF	20	1.30	0.47	
Alopecia				
AC	22	2.18	0.80	.034
CMF	18	1.67	0.69	
Number of trips				
AC	22	1.82	0.80	.000
CMF	20	2.80	0.41	
Experience of a friend				
AC	21	2.76	0.54	.009
CMF	20	2.10	0.91	

According to the list of factors, the whole sample and the AC group rated maintaining your normal routine as very important the most often. The CMF group rated overall side effects and vomiting as very important the most often. Using *t*-tests, six factors were found to be rated significantly different in importance by the women who chose AC and those who chose CMF (Table 4). The CMF group rated overall side effects, nausea, vomiting, alopecia, and the experience of a friend as more important than the AC group. The AC group rated the number of required trips to the centre as more important than the CMF group.

4. Discussion

Shared decision making is increasingly advocated as the ideal model for clinical decision making. The decision regarding the type of adjuvant chemotherapy for premenopausal women with axillary node positive breast cancer is complex as some regimens have been shown to have equal efficacy with different toxicity profiles. For the choice between AC and CMF, a patient must trade off a shorter treatment regimen (AC) with potentially worse toxicity versus a longer treatment schedule with potentially milder toxicity (CMF). Our objective was to develop an instrument to help clinicians transfer information regarding the benefits and risks of these two regimens. Previous instruments had been developed for women regarding the choice of additional treatment versus no further treatment. The context around this decision was felt to be different, involving the choice between two types of chemotherapy, AC and CMF.

Our results demonstrate that the instrument was acceptable. All patients consented to participate. The educational value of the instrument is shown by the high level of accuracy that was obtained when comprehension was tested. Women found the Decision Board particularly helpful in making a decision about treatment. Patients uniformly indicated that the doctor or nurse did not influence their choice suggesting that when patients are empowered in decision making, the physician's influence may be less important [14]. Application of the Decision Board was found to be feasible within a regional adult outpatient breast cancer clinic. The nurses in the clinic

administered the Decision Board in no greater time than is usually required for patient teaching in order to fulfil informed consent. Clinician feedback regarding the feasibility of the Board in a busy outpatient setting was positive.

Treatment choice was split fairly evenly between AC and CMF and was not predictable by demographic factors. It was also not influenced by the order of presentation of treatment choices. While this group of women chose between two equally effective adjuvant chemotherapy regimens, it appears that for most participants their treatment decision depended upon the outcome of how each individual weighed the importance of two issues, the side effects and time. For a woman thinking about the value each one held, safety and risk were important considerations. Generally, a woman who chose AC was willing to take a greater chance that she may experience the side effects for the advantage of being finished treatment in a shorter period of time. Whereas a woman who chose CMF appeared to be more averse to the risk of side effects and less concerned about time. Maintaining quality of life was expressed by all women as an important consideration related to their chemotherapy choice.

The impact on quality of life is perhaps the most interesting and revealing reason for treatment choice. It was a popular reason for treatment choice for both the women who chose AC and those who chose CMF. This finding validates the decision-making process since the differences between the two chemotherapy regimens revolve around quality of life issues such as the treatment schedule and side effects. These results support the fact that quality of life is subjective and can only be defined by the individual based upon what he/she believes matters most. It is evident that there were various perspectives among the women about the meaning of the different characteristics of the chemotherapy regimens.

We also found an unexpected association between the type of breast cancer surgery a woman underwent and her choice of chemotherapy. This association may have resulted for several reasons. Adriamycin associated with several side effects may have been interpreted as more aggressive chemotherapy. Women who preferred more radical surgery may have been more inclined to prefer AC chemotherapy.

Additionally, breast conserving surgery is usually accompanied by radiation therapy extending the length of primary treatment as compared to mastectomy which is usually not followed by radiation treatment. Women who preferred a shorter duration of primary therapy may also have been more inclined to choose AC chemotherapy. Since it is unclear if all women in our sample were offered a choice of surgery, these reasons remain speculative.

With any study, there are limitations associated with the design and method chosen. Important limitations here include a relatively small sample size and the lack of a control group in which the decision aid was not used which limits our ability to generalize the results to other groups and to comment on clinical application. Previous studies have suggested problems with the traditional physician-patient consultation in communication regarding the benefits and risks of chemotherapy [20] and involvement in decision making [21] for women with breast cancer. The objective of this study was to look at the feasibility of using a decision aid in this particular context and to assess some of the factors that may influence the decision. Our results are supportive for the use of the Decision Board approach in this situation, but further evaluation in a randomized trial would help clarify the role of the Decision Board in improving patient understanding and satisfaction with decision making.

It is important to note that some studies have found that not all patients wish to participate in treatment decision making [1,5] and that health care professionals may overestimate the degree of involvement that patients desire [22]. However, within the area of oncology, particularly breast cancer, a greater emphasis has been placed on quality of life issues as defined by the individual patient, and the literature does provide support that young women with breast cancer are among those who do desire a more active role in treatment decision making. Future research should acknowledge the different levels of participation desired by patients. It is important to continue to measure the level of difficulty with treatment decisions in order to learn more about decision-making styles and behaviours and in particular, about individuals who have difficulty with the decision-making process. Education will continue to have an important role to play in increasing

patient understanding and participation in one's own health care.

Acknowledgements

























This work was supported by: The Canadian Breast Cancer Foundation (Fellowship Fund). We acknowledge the following individuals for their support and assistance with this research: Darlyne Rath as an advisor; Rosemary Russell, Patricia Burch, Doug May, Susan Knight, Sue Clarkson, Lorraine Martelli-Reid, Cheryl Broadfield, Ed Chouinard, and Mark Levine as the nurses and physicians of the clinic; and Rachael Green and John Holland for their graphic artistic talents in constructing the Decision Board.

References

- [1] Cassileth BR, Zupkis RV, Sutton-Smith MS, March V. Information and participation preferences among cancer patients. *Ann Int Med* 1980;92:832-6.
- [2] Greenfield S, Kaplan S, Ware JE. Effects on blood sugar control and quality of life in diabetes. *J Gen Intern Med* 1985;3:448-57.
- [3] Degner LF, Russell CA. Preferences for treatment control among adults with cancer. *Res Nurs Health* 1988;11:367-74.
- [4] Blanchard CG, Labrecque MS, Ruckdeschel JC, Blanchard EB. Information and decision-making preferences of hospitalized adult cancer patients. *Soc Sci Med* 1988;27:1139-45.
- [5] Degner LF, Sloan JA. Decision making during serious illness: what role do patients really want to play? *J Clin Epidemiol* 1992;45:941-50.
- [6] Ende J, Kazis L, Ash A, Moskowitz MA. Measuring patients' desire for autonomy: decision making and information-seeking preferences among medical patients. *J Gen Int Med* 1988;4:23-30.
- [7] Owens RG, Ashcroft JJ, Leinster SJ, Slade PD. Informal decision analysis with breast cancer patients: an aid to psychological preparation for surgery. *J Psychosoc Oncol* 1987;5:23-33.
- [8] Morris J, Ingham R. Choice of surgery for early breast cancer: Psychosocial considerations. *Soc Sci Med* 1988;27:1257-62.
- [9] Morris J, Royle GT. Offering patients a choice of surgery for early breast cancer: a reduction in anxiety and depression in patients and their husbands. *Soc Sci Med* 1988;26:583-5.
- [10] Ward S, Heidrich S, Wolberg W. Factors women take into account when deciding upon type of surgery for breast cancer. *Cancer Nurs* 1989;12:344-51.
- [11] Early Breast Cancer Trialists' Collaborative Group. Systemic treatment of early breast cancer by hormonal, cytotoxic, or immune therapy. *Lancet* 1992;339:71-85.
- [12] Fisher B, Brown AM, Dimitrov NV, Poisson R, Redmond C, Margolese RG, et al. Two months of doxorubicin-1-cyclophosphamide with and without interval reinduction therapy compared with six months of cyclophosphamide, methotrexate, and fluorouracil in positive-node breast cancer patients with tamoxifen-nonresponsive tumors: results from the National Surgical Adjuvant Breast and Bowel Project B-15. *J Clin Oncol* 1990;8:1483-96.
- [13] Levine MN, Gafni A, Markham B, MacFarlane D. A bedside decision instrument to elicit a patient's preference concerning adjuvant chemotherapy for breast cancer. *Ann Int Med* 1992;117:53-8.
- [14] Whelan TJ, Levine MN, Gafni A, Lukka H, Mohide EA, Patel M, et al. Breast irradiation postlumpectomy: development and evaluation of a decision instrument. *J Clin Oncol* 1995;13:847-53.
- [15] Sebban C, Browman G, Gafni A, Norman G, Levine M, Assouline D, et al. Design and validation of a bedside decision instrument to elicit a patient's preference concerning allogeneic bone marrow transplantation in chronic myeloid leukemia. *Am J Hematol* 1995;48:221-7.
- [16] Bonnetterre J, Chevallier B, Metz R, Fargeot P, Pujade-Lauraine E, Spielmann M, et al. A randomized double-blind comparison of ondansetron and metoclopramide in the prophylaxis of emesis induced by cyclophosphamide, fluorouracil, and doxorubicin or epirubicin chemotherapy. *J Clin Oncol* 1990;8:1063-9.
- [17] Osoba D, Warr DG, Fitch MI, Nakashima L, Warren B. Guidelines for the optimal management of chemotherapy-induced nausea and vomiting: a consensus. *Can J Oncol* 1995;5:381-400.
- [18] Woodward C.A., Chambers L.W. Guide to Questionnaire Construction and Question Writing, 3rd ed. Ottawa, ON: The Canadian Public Health Association, 1986.
- [19] Redman BK. The Process of Patient Education, 6th ed. Toronto, ON: CV Mosby, 1988:150-1.
- [20] Siminoff LA, Fetting JH, Aeloff MD. Doctor-patient communication about breast cancer adjuvant therapy. *J Clin Oncol* 1989;7:1192-200.
- [21] Degner LF, Kristjanson LJ, Bowman D, et al. The patient-physician relationship. Information needs and decisional preferences in women with breast cancer. *J Am Med Assoc* 1997;277:1485-92.
- [22] Strull WM, Lo B, Charles G. Do patients want to participate in medical decision making? *J Am Med Assoc* 1984;252:2990-4.

Appendix 6: Panels from Node-positive Instrument

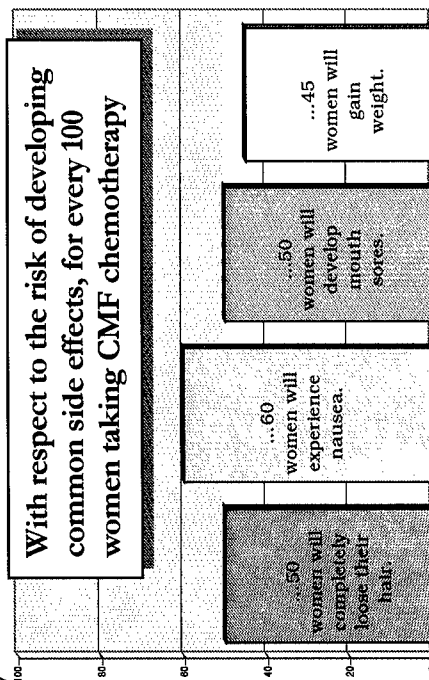
CMF Treatment Cycle

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1	 						
Week 2	 						
Week 3			No Chemotherapy	No Chemotherapy	No Chemotherapy		
Week 4			No Chemotherapy	No Chemotherapy	No Chemotherapy		

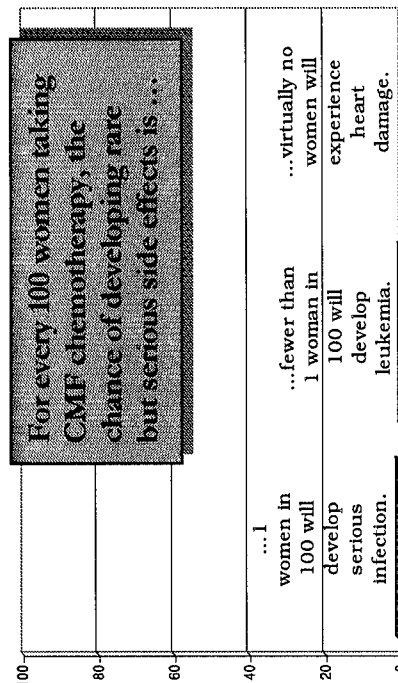
- Each "treatment cycle" lasts 4 weeks.
- 3 chemotherapy drugs are given during each *treatment cycle*:
 - **Cyclophosphamide** is taken by mouth (pills) at home every day for the first 2 weeks of every *treatment cycle*, and
 - **Methotrexate** and **Fluorouracil** are given intravenously (through a needle) during clinic visits at the start of each *treatment cycle* and again one week later. It takes about 20 minutes to receive the intravenous drugs.
- The *treatment cycle* is repeated 6 times for a total of 6 months.

C M F

Side Effects of CMF Chemotherapy













- ♦ While only half (50 in 100) of the women taking CMF completely loose their hair, most will experience some degree of hair thinning.
- ♦ Women taking CMF are more likely to gain weight than those taking AC or CEF.



- ♦ When compared to other chemotherapy options, women taking CMF are least likely to experience serious side effects such as infection (1 in 100 women), leukemia (1 in 200 women) and heart damage (almost zero).

A C

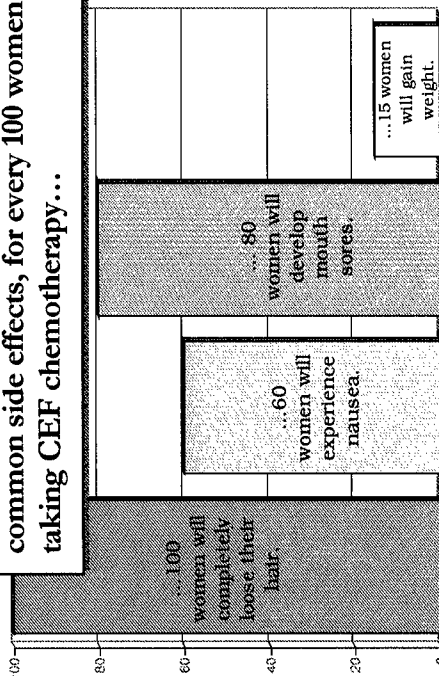
AC Treatment Cycle

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1			 No Chemotherapy				
Week 2			No Chemotherapy				
Week 3			No Chemotherapy				

- Each "treatment cycle" lasts 3 weeks.
- 2 chemotherapy drugs are given during each treatment cycle:
 - **Adriamycin** and **Cyclophosphamide** are given intravenously (through a needle) during a single clinic visit at the beginning of each treatment cycle. It takes about 60 minutes to receive the intravenous drugs.
- The *treatment cycle* is repeated 4 times for a total of 2½ months.

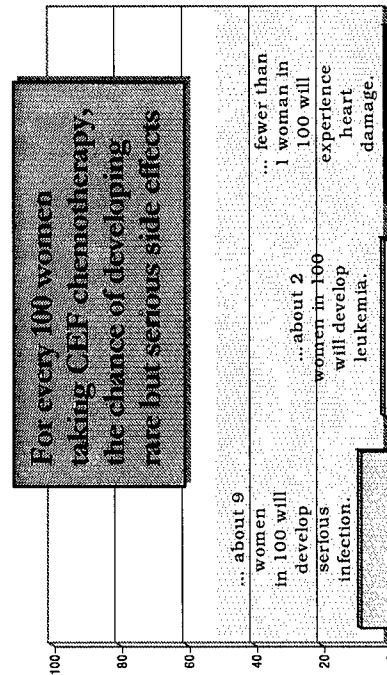
Side Effects of CEF Chemotherapy

With respect to the risk of developing common side effects, for every 100 women taking CEF chemotherapy...



- ♦ Virtually all women taking CEF loose their hair.
- ♦ Nausea is more common among women taking CEF than those taking AC.
- ♦ Compared to CMF and AC, mouth sores happen most frequently among women taking CEF.
- ♦ Women taking CEF are less likely to gain weight than those taking CMF.

- ♦ The chance of experiencing serious side effects such as infection (17 in 200 women), leukemia (3 in 200 women) and heart damage (1 in 200 women) is slightly higher than with CMF or AC.



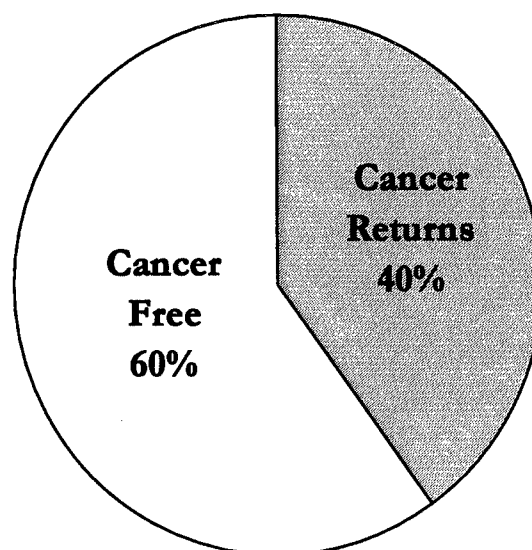
CANCER - FREE

- ♦ All tests and examinations in the coming five years show that you are free of cancer.
- ♦ You continue to be followed at the Cancer Clinic beyond five years.
- ♦ Even though all the examinations show you are cancer free, from time to time, you may worry about the cancer coming back.

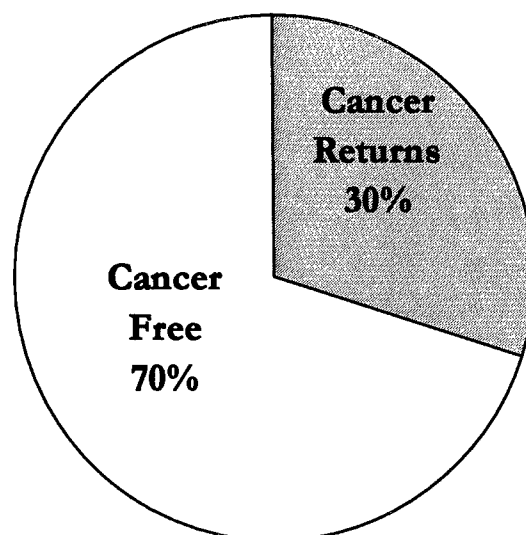
CANCER RETURNS

- Breast cancer may come back in the next five years.
- Breast cancer can come back in the same breast or on the chest wall (local recurrence).
 - When cancer returns in the breast or on the chest wall, it is often seen as a small lump. The lump is painless but may cause worry and upset. It is usually removed by a surgeon.
 - Recurrence of cancer in the breast or chest wall is rare and can often be successfully treated.
- Breast cancer can come back in other parts of the body, such as the bone, liver or lung (distant recurrence).
 - Many women whose cancer comes back in other parts of the body receive further treatment: chemotherapy, hormonal therapies, radiation therapy, and/or pain medicine.
 - Unfortunately, a patient whose breast cancer comes back in other parts of the body can be treated but usually cannot be cured.









AC

























































































































CEF



Appendix 7: Panels from Surgery instrument

Decision Board (C) Copyright 1998-99 Seibald, Whelan, Galin				
				
	Description of Choice	Side Effects of Choice	Results of Choice: for Breast	Results of Choice: for Survival
Mastectomy	Mastectomy	Disfigurement	Reconstruction	Prevention of Recurrence
Lumpectomy plus Radiation	Lumpectomy	Disfigurement	Mastectomy	Prevention of Recurrence
General Info	General Info	General Info	General Info	General Info
       3:44 PM				

Description of Choice		Side Effects of Choice	Results of Choice: for Breast	Results of Choice: for Survival
MASTECTOMY <i>Description</i>				
MASTECTOMY: Surgical Removal of the Breast				
<ul style="list-style-type: none"> • Entire breast will be removed • Some lymph nodes under your arm will be removed • You are left with a healing scar that runs across your chest • A drain is inserted near the scar under the arm, for 5-10 days, to remove excess fluid • After surgery, you may be referred to the Cancer Centre for consideration of other treatments (hormonal therapy or chemotherapy) • Radiation is not normally required 				
Lumpectomy plus Radiation				
General Info				

Description of Choice		Side Effects of Choice	Results of Choice: for Breast	Results of Choice: for Survival
<div> <div>                               </div> <div>                               </div> </div>			<div> <div>                               </div> <div>                             </div></div>	

Decision Board (C) Copyright 1998-99 Seabold, Whelan, Gafni

	Description of Choice	Side Effects of Choice	Results of Choice: for Breast	Results of Choice: for Survival
Mastectomy	<div> <div></div> <div></div> <div></div> <div></div> </div>	<div> <div></div> <div></div> <div></div> <div></div> </div>	<div> <div></div> <div></div> <div></div> <div></div> </div>	<div> <div></div> <div></div> <div></div> <div></div> </div>
<div> <div></div> <div></div> <div></div> <div></div> </div>	<p>MASTECTOMY <i>Results for Survival</i></p>			
<div> <div></div> <div></div> <div></div> <div></div> </div>	<p>Your chance of surviving cancer is the SAME as with Lumpectomy plus Radiation</p>			
<div> <div></div> <div></div> <div></div> <div></div> </div>	<p>General Info</p>			

Start | Exploring - Printers | Document1 - Microsoft Word | Control Panel | 3:38 PM

Decision Board (L) Copyright 1998-99 Sebaldt, Whelan, Gafni

Description of Choice	Side Effects of Choice	Results of Choice: for Breast	Results of Choice: for Survival
<div data-bbox="375 363 505 491" data-label="Image"> </div>	<div data-bbox="375 491 505 693" data-label="Image"> </div>	<div data-bbox="375 693 505 1019" data-label="Image"> </div>	<div data-bbox="375 1019 505 1168" data-label="Image"> </div>
<div data-bbox="505 363 618 491" data-label="Image"> </div>	<div data-bbox="505 491 618 693" data-label="Image"> </div>	<div data-bbox="505 693 618 1019" data-label="Image"> </div>	<div data-bbox="505 1019 618 1168" data-label="Image"> </div>
<div data-bbox="618 363 748 491" data-label="Image"> </div>	<div data-bbox="618 491 748 693" data-label="Image"> </div>	<div data-bbox="618 693 748 1019" data-label="Image"> </div>	<div data-bbox="618 1019 748 1168" data-label="Image"> </div>
<div data-bbox="748 363 878 491" data-label="Image"> </div>	<div data-bbox="748 491 878 693" data-label="Image"> </div>	<div data-bbox="748 693 878 1019" data-label="Image"> </div>	<div data-bbox="748 1019 878 1168" data-label="Image"> </div>
<div data-bbox="878 363 1008 491" data-label="Image"> </div>	<div data-bbox="878 491 1008 693" data-label="Image"> </div>	<div data-bbox="878 693 1008 1019" data-label="Image"> </div>	<div data-bbox="878 1019 1008 1168" data-label="Image"> </div>
<div data-bbox="1008 363 1138 491" data-label="Image"> </div>	<div data-bbox="1008 491 1138 693" data-label="Image"> </div>	<div data-bbox="1008 693 1138 1019" data-label="Image"> </div>	<div data-bbox="1008 1019 1138 1168" data-label="Image"> </div>
<div data-bbox="1138 363 1268 491" data-label="Image"> </div>	<div data-bbox="1138 491 1268 693" data-label="Image"> </div>	<div data-bbox="1138 693 1268 1019" data-label="Image"> </div>	<div data-bbox="1138 1019 1268 1168" data-label="Image"> </div>
<div data-bbox="1268 363 1398 491" data-label="Image"> </div>	<div data-bbox="1268 491 1398 693" data-label="Image"> </div>	<div data-bbox="1268 693 1398 1019" data-label="Image"> </div>	<div data-bbox="1268 1019 1398 1168" data-label="Image"> </div>

Decision Board (L) Copyright 1998-99 Sebaldt, Whelan, Gafni

Start | Exploring - Pictures | Document1 - Microsoft Word | Control Panel | 3:40 PM



MASTECTOMY

MASTECTOMY: *Surgical Removal of the Breast*

- Entire breast will be removed
- Some lymph nodes under your arm will be removed
- You are left with a healing scar that runs across your chest
- A drain is inserted near the scar under the arm, for 5-10 days, to remove excess fluid
- After surgery, you may be referred to the Cancer Centre for consideration of other treatments (hormonal therapy or chemotherapy)
- Radiation is not normally required

LUMPECTOMY plus RADIATION

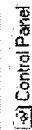
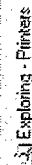
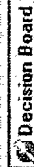


LUMPECTOMY: *Surgical Removal of the Cancerous Lump*

- Often, a drain is inserted near the scar under the arm, for 5-10 days, to remove excess fluid
- Some of the lymph nodes under your arm will be removed
- You are left with two healing scars, one on the breast and one under the arm
- Only the cancerous lump and some surrounding tissue will be removed
- In some instances (in about 1 out of 10 women), all the cancer in the breast may not be removed and you may require further surgery
- Once the breast has healed, 3-4 weeks after surgery, you will be referred to the Cancer Centre for consideration of radiation

RADIATION: *X-ray treatment*

- You will need to come to the Cancer Centre for planning of the radiation and for treatments
- Your treatments will be daily for 5 weeks, excluding weekends
- Each visit lasts approximately 30 to 45 minutes
- The time between your surgery and the beginning of your radiation treatments may be 6-12 weeks
- Other treatments (hormonal therapy and chemotherapy) may be considered
- If you are treated with chemotherapy, your radiation will begin after chemotherapy



Decision Board (C) Copyright 1998-99 Sebaldt, Whelan, Gahn				
Description of Choice		Side Effects of Choice	Results of Choice: for Breast	Results of Choice: for Survival
Mastectomy		<ul style="list-style-type: none"> • Side effects of surgery e.g. numbness, pain 	<ul style="list-style-type: none"> • Loss of the breast • Occasionally cancer will come back 	<ul style="list-style-type: none"> • Your chance of surviving cancer is the same as with Lumpectomy plus Radiation
Lumpectomy plus Radiation		<ul style="list-style-type: none"> • Side effects of surgery e.g. numbness, pain • Side effects of radiation e.g. redness of the skin 	<ul style="list-style-type: none"> • Scar on the breast • Occasionally cancer will come back 	<ul style="list-style-type: none"> • Your chance of surviving cancer is the same as with Mastectomy
General Info		Introduction: <ul style="list-style-type: none"> • Two choices for the removal of your cancer by surgery 	The Decision Board: <ul style="list-style-type: none"> • To help you make the best decision 	Summary: <ul style="list-style-type: none"> • The chance for survival is the same for both treatment choices